Arnold B. Calmann (abc@saiber.com)
Jakob B. Halpern (jhalpern@saiber.com)
Catherine Soliman (csoliman@saiber.com)
Saiber LLC
One Gateway Center, Suite 950
Newark, NJ 07102
T: (973) 622-3333
F: (973) 286-2465

Stuart A. Williams (swilliams@wsgr.com)
Michael S. Sommer (msommer@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI, P.C.
1301 Avenue of the Americas,
40th Floor
New York, NY 10025
Telephone: (212) 999-5800
Facsimile: (212) 999-5899

Seth C. Silber (ssilber@wsgr.com)
Brendan J. Coffman (bcoffman@wsgr.com)
Thu V. Hoang (thoang@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI, P.C.
1700 K Street NW, 5th Floor
Washington, DC 20006
Telephone: (202) 973-8800
Facsimile: (202) 973-8899

Attorneys for Plaintiff Mylan Pharmaceuticals Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC., Plaintiff, v. TEVA PHARMACEUTICALS INDUSTRIES LTD, TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES & MARKETING, INC., Defendants.	**Civil Action No**. **COMPLAINT AND JURY DEMAND** Document filed electronically

Plaintiff Mylan Pharmaceuticals Inc. ("Mylan") brings this Complaint against Teva Pharmaceuticals Industries Ltd. ("Teva Ltd."), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Neuroscience, Inc. ("Teva Neuro"), and Teva Sales & Marketing, Inc. ("Teva S&M") (collectively "Teva"), by and through their counsel, and allege as follows:

INTRODUCTION

1. This is an action under the Sherman Act, the Lanham Act and New Jersey state law arising out of Teva's anticompetitive and illegal scheme to delay and mute effective competition to its multiple sclerosis ("MS") treatment Copaxone® (glatiramer acetate or "GA" injection). Teva, best known as the world's largest manufacturer of generic drugs, was in an unusual position with respect to its branded drug Copaxone. Specifically, Copaxone put Teva in the position of delaying and foreclosing, rather than championing, generic competition.

2. Indeed, as a district court recently found, since Copaxone's first approval for marketing in the United States in 1996, "Teva has pursued every available avenue to prevent other glatiramer acetate products from coming to market." *Teva Pharm. USA, Inc. v. FDA*, Civil Action No. 20-808 (BAH), 2020 U.S. Dist. LEXIS 245082, at *23 (D.D.C. Dec. 31, 2020).

3. Teva's comprehensive and sophisticated scheme has endured more than a decade. Its tactics were and are directed in large part at Mylan, Teva's rival in the generic pharmaceutical business and the primary threat to Teva's Copaxone franchise. Faced with the threat of generic competition, Teva responded by relying on a series of tactics to delay Mylan's launch, including by abusing the regulatory and court processes (including suits against the FDA in 2014 and 2020 to thwart approval and adoption of generic versions of Copaxone), and preventing uptake of Mylan's bioequivalent product after it finally launched. Teva's playbook worked perfectly: it delayed Mylan from launching its competitive product, substantially impeded Mylan from making sales of its product to patients despite offering a significantly lower-cost alternative to Copaxone, and enabled Teva to enjoy substantial ill-gotten gains at the expense of patients, insurers, and the government.

4. Mylan's concerns were confirmed by a recent detailed report of the United States Congress. A September 2020 report by the Committee on Oversight and Reform of the United States House of Representatives ("House Teva Report") lays bare the extent of Teva's malfeasance and confirms that Teva's scheme had both the intent and effect of perpetuating Teva's monopoly at the expense of Teva's competitors and – most acutely – American consumers.[1]

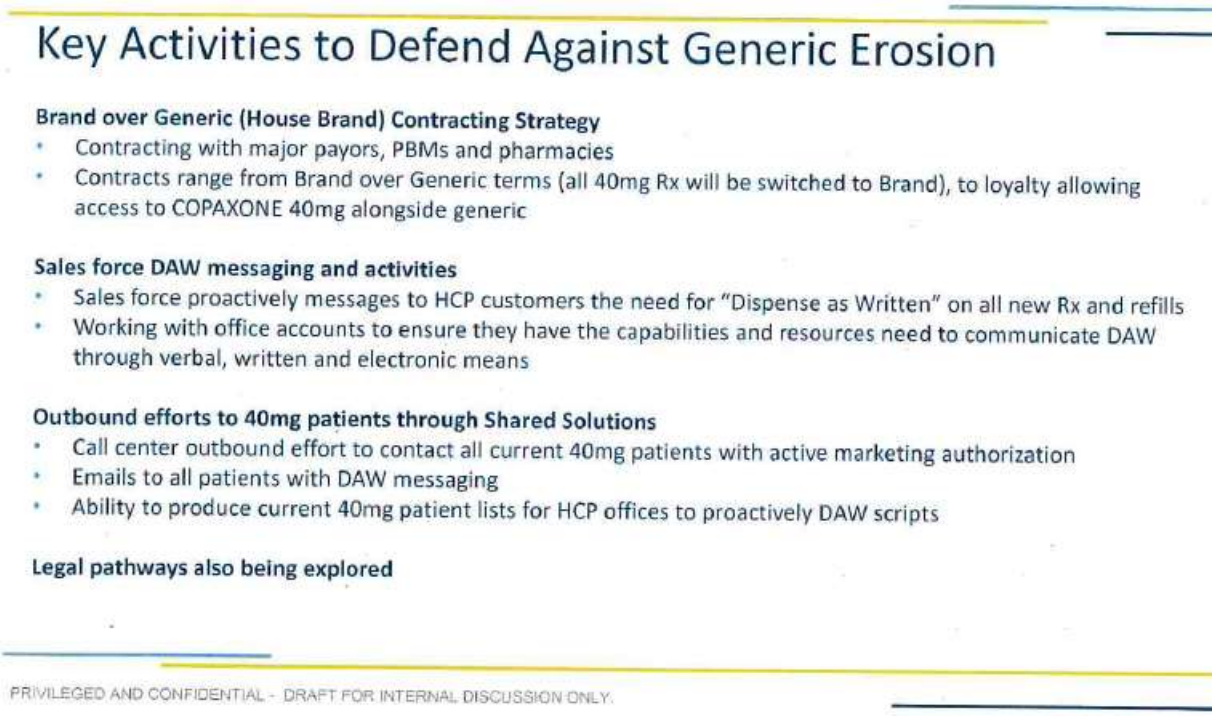
5. Entitled "Drug Pricing Investigation: Teva-Copaxone," the House Teva Report included evidence from documents produced by Teva and reported, among other things, the following conclusions in its Executive Summary:

- "**Harm to Patients**: Teva's price increases on Copaxone have resulted in thousands of dollars in out-of-pocket costs for U.S. patients and have left many unable to afford the drug. A recent study found that the median annual out-of-pocket cost for a Medicare patient on Copaxone was $6,672 in 2019. Even Teva's own employees could not afford Copaxone at its price. In one July 2018 exchange, a Teva employee explained that she could no longer afford Copaxone because she would have to pay $1,673.33 out of pocket as compared to $12 for Mylan's generic product. Ultimately, Teva gave the employee free product, a solution unavailable to most Copaxone patients."

- "**New Dosage as 'Generic Defense Strategy'**: In 2014, Teva introduced a 40 mg/ml formulation of Copaxone in part to extend its monopoly pricing for Copaxone by shifting patients to that formulation—which still enjoyed market exclusivity—before the 20 mg/ml formulation began facing lower-priced generic competition. To push patients to the 40 mg/ml formulation of Copaxone, Teva increased the price of the 20 mg/ml formulation. To press patients to make the move, Teva explored a plan to 'Discontinue 20mg Financial Programs (Patient Services),' its financial assistance program for patients. Teva's strategy was successful in maintaining its profits and limiting competition. Experts estimate that the strategy cost the U.S. health care system between $4.3 and $6.5 billion in excess spending."

[1] The House Teva Report report is available at COMMITTEE ON OVERSIGHT AND REFORM, U.S. HOUSE OF REPRESENTATIVES, DRUG PRICING INVESTIGATION: TEVA- COPAXONE, (2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Teva%20Staff%20Report%2009-30-2020.pdf and the accompanying document packet ("House Teva Report Document Packet") is available at COMMITTEE ON OVERSIGHT AND REFORM, U.S. HOUSE OF REPRESENTATIVES, DRUG PRICING INVESTIGATION: TEVA- COPAXONE, (2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Document%20Packet%20Teva%209-30-2020.pdf. These documents are incorporated herein by reference.

- "**Exclusionary Tactics to Limit Generic Competition**: After Mylan introduced a lower-priced generic version of Copaxone 40 mg/ml in October 2017, Teva implemented several new exclusionary tactics to limit generic competition and maintain profits. First, Teva contracted with specialty pharmacies and pharmacy benefit managers to limit generic substitution. Second, Teva lobbied doctors to write prescriptions for Copaxone that prohibited generic substitution. Third, Teva used its patient programs to convince patients to remain on the more expensive brand name version of the drug. Teva summarized these strategies in the following slide to its Board of Directors:"



Key Activities to Defend Against Generic Erosion

Brand over Generic (House Brand) Contracting Strategy

- Contracting with major payors, PBMs and pharmacies
- Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic

Sales force DAW messaging and activities

- Sales force proactively messages to HCP customers the need for "Dispense as Written" on all new Rx and refills
- Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means

Outbound efforts to 40mg patients through Shared Solutions

- Call center outbound effort to contact all current 40mg patients with active marketing authorization
- Emails to all patients with DAW messaging
- Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts

Legal pathways also being explored

PRIVILEGED AND CONFIDENTIAL - DRAFT FOR INTERNAL DISCUSSION ONLY.

6. Teva's conduct to impede generic competition began before the creation of this presentation in 2017. Over the years, faced with the prospect of competition from Mylan and other generic manufacturers, Teva employed a concerted, multi-pronged anticompetitive scheme to systematically delay and foreclose generic competition in the market for GA. Specifically, Teva:

- Repeatedly abused the regulatory process before the Food and Drug Administration ("FDA") and legal processes to delay generic entry;

- Switched the market from the 20mg Copaxone product to the 40mg product only because Teva believed it had patent protection over the 40mg product;

- Employed economically irrational pricing and anticompetitive agreements with other industry stakeholders to shift consumers to Teva's 40mg product in anticipation of 20mg generic entry;

- Entered into "House Brand" agreements with pharmacy benefit managers ("PBMs") and PBM-owned specialty pharmacies to exclude generic GA from formularies. These agreements went beyond typical, procompetitive rebating practices. Instead, they prevented and continue to prevent generic GA from being covered by insurance, and exclude generic GA from dispensing at the pharmacy level, even if the prescription specifically calls for generic GA and even if the generic GA is covered on formulary, such that generic GA is unable to compete on price;

- Drafted and propagated a playbook of false and misleading statements designed to dissuade health care providers and MS patients from accepting generic GA as part of a campaign to persuade doctors to prescribe, and patients to request, branded Copaxone "dispense as written" ("DAW"); and

- Used illegal kickbacks through purported "donations" to third-party foundations to prevent patients from switching to generic GA.

7. Teva's anticompetitive scheme delayed generic entry for years, significantly blunted the impact of generic entry, reduced the generic uptake rate, and caused as much as hundreds of millions of dollars per quarter in consumer harm. But for Teva's illegal conduct, generic competition would have entered the market years earlier and significantly reduced drug costs to consumers. That delayed entry has significantly impeded and continues to impede consumer access to Mylan's generic GA product.

8. Copaxone was and is critical to Teva. It represented 19% of the company's 2017 global revenue and peaked at approximately $3.36 billion in U.S. revenue in 2016. Teva admitted in a court filing that it "stands to lose hundreds of millions of dollars *within* months of FDA approving the launch of a putative generic version of Copaxone®" (emphasis in original).

9. Since at least 2008, Teva carried out a repetitive and continuous strategy to abuse the regulatory processes before the FDA and court filings to delay generic entry. Subsequently, taking advantage of the delay caused by its conduct, Teva bought enough time to launch a three-

times-a-week 40mg dosage of Copaxone in 2014. When the FDA approved a generic formulation of Copaxone 20mg owned by Sandoz in April 2015, Sandoz's entry was of minimal benefit to consumers because, as the FDA observed in defending against a lawsuit by Teva to prevent the FDA from approving GA ANDAs, Teva had "vigorously convert[ed]" patients to Teva's 40mg formulation that did not face generic competition.

10. Teva switched the market to the 40mg dosage to avoid competition from generic 20mg products, which would be automatically substitutable for Teva's Copaxone 20mg. Teva carried out this strategy through several steps. First, Teva priced the 40mg product lower than 20mg, which would be economically irrational but for the exclusion of generic competition.[2] Second, to further widen the price gap between the 40mg and 20mg products and drive more patients to the 40mg product, Teva increased the price of 20mg Copaxone. Third, Teva entered into agreements with PBMs whereby it paid PBMs to lobby doctors to prescribe only the 40mg product and conditioned certain rebates payments to the PBMs on them agreeing to put the 40mg product on their formularies, thus accelerating the switch to the 40mg product.

11. This strategy was successful for Teva: as of December 2015, Teva had converted nearly 77% of Copaxone patients to the 40mg product, which did not face generic competition, and severely impeded competition from any generic 20mg product. In addition, Teva also sought patent protections for the frequency of the new 40mg dosage to extend its monopolization on Copaxone, but those patents were later invalidated by the Patent Trial and Appeal Board ("PTAB"), district court, and Court of Appeals for the Federal Circuit.

12. Teva furthered its complex scheme by contracting with intermediaries, including PBMs and PBM-owned specialty pharmacies, to prevent uptake of any generic product, including Mylan's generic GA. In the pharmaceutical industry it is both common and usually procompetitive for a brand to offer rebates to purchasers in exchange for preferred and even

[2] Normally, a company would price a better product higher than an inferior product to reflect the increased value. Given Teva's claim that the 40mg product is better than the 20mg product in certain manners, pricing the 40mg *lower* than the 20mg product appears economically irrational.

exclusive placement on formularies created by PBMs. *See, e.g.*, *In Re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*, No. 2:17-md-02785, Dkt. No. 2254 (D. Kan. Dec. 17, 2020). Teva's conduct went far beyond those practices that are both typical and procompetitive in ways that transform Teva's conduct from competition on the merits to illegal exclusion and monopolization. Teva's intermediary strategy included three components: i) conducting a misrepresentation campaign to prevent the writing of generic GA scripts; ii) creating agreements with PBMs and specialty pharmacies (usually housed under the same corporate parent) that promised additional rebates to switch any generic script to branded Copaxone, thereby preventing pharmacies from dispensing a competing generic product; and iii) coercing adoption of Teva's pricing and rebating scheme by offering all-or-nothing rebates, dooming any attempt to compete on price by any generic, including Mylan, to inevitable failure.

13. First, Teva prevented doctors from writing scripts that would allow for generic substitution. Teva embarked on a campaign to increase DAW prescriptions that ensure the brand product, Copaxone, would be sold by pharmacies instead of allowing pharmacies to substitute Mylan's generic product. To accomplish this, Teva openly and knowingly lied to doctors regarding the substitutability, efficacy, safety profile, and patient support services for generic GA products, disregarding the FDA's determination that Mylan's generic GA was therapeutically equivalent to Copaxone. Specifically, leading up to the launch of Mylan's GA and for at least months thereafter, Teva made false and misleading statements designed to deceive Copaxone prescribers and MS patients into believing that Mylan's product is less effective than Copaxone, or does not come with patient support comparable to Copaxone. Teva made these false and misleading statements with the intention of influencing prescribers to keep their patients on Copaxone rather than allowing for generic substitution, or to switch them back to Copaxone if they had been automatically switched to Mylan's generic GA.

14. In conjunction with this misrepresentation campaign, Teva introduced illegal kickbacks through purported "donations" to third-party foundations to pay off the copay obligations of Medicare Part D patients. Teva has been making these payments for years, and

they have now become another tool to impede generic competition. Specifically, these payments further dissuade a substantial number of patients from switching to generic GA because Teva removed the perceived price difference between branded Copaxone and generic GA to patients (even though payers and the government are still forced to pay the higher price for Copaxone instead of more affordable generic GA). Teva's illegal kickbacks through purported "donations" to the third-party foundations for Medicare Part D patients are the subject of an on-going lawsuit filed by the Department of Justice ("DOJ"), and the House Teva Report found that this conduct continues today.[3]

15. The combination of these efforts caused the rate of DAW prescriptions for Copaxone to skyrocket from 13% in the years before Mylan's 40mg GA launched to at least 77% just four months after Mylan's entry. For at least months after Mylan's entry, doctors and nurses around the country refused to even speak with Mylan sales representatives about Mylan's GA and related services because they had already been deceived into believing Mylan's product was less effective and did not come with copay or nursing support.

16. The Congressional investigation also uncovered evidence that Teva's illegal kickbacks to subsidize Medicare Part D patients' copay effectively reduced competition. For example, in a January 2018 internal email, Teva's Executive Vice President for North America explained why an insurer's attempt to facilitate conversion to generic GA by putting branded Copaxone on non-preferred tier failed: "Also, the NP [non-preferred] status means little as we buy the patients [sic] copay down to zero anyway. Unless they NDC block Copaxone 40mg, we are fine . . . the actual impact is very low . . ." However, while Teva insulated itself from generic

[3] Relatedly, a whistleblower lawsuit brought by former Teva sales representatives alleged that Teva bribed doctors in the United States with payments of thousands of dollars to prescribe Copaxone. This allegation survived a motion for summary judgment and Teva settled the lawsuit for $54 million in January 2020. McEldrew Young, PRNewswire, *Breaking Legal News: TEVA Agrees to Pay $54 Million to Settle McEldrew Young False Claims Act Qui Tam Whistleblower Lawsuit* (Jan. 6, 2020), https://www.prnewswire.com/news-releases/breaking-legal-news-teva-agrees-to-pay-54-million-to-settle-mceldrew-young-false-claims-act-qui-tam-whistleblower-lawsuit-300981790.html.

competition, the insurer was forced to continue to pay the unsubsidized price of branded Copaxone despite its clear preference for and attempt to switch patients to lower-priced generic GA.

17. Second, Teva illegally leveraged its relationship with intermediaries to prevent the dispensing of generic GA. Teva was fully aware that generic competitors would compete on price, including by lowering the list price for generic GA and competing on formulary placement with PBMs. To forestall this competition, Teva entered into agreements that removed even the possibility of this competition. Key to these agreements were all-or-nothing rebates across both Copaxone dosages and a "special contract" with specialty pharmacies tied to PBMs to replace any would-be generic with Copaxone, *even if the prescription specifically called for generic GA*, in exchange for additional rebates. Unlike brand-vs-brand competition for particular therapeutic categories, where competition tends to occur at the formulary level, Teva's conduct with respect to the PBMs and specialty pharmacies meant that Mylan could not compete regardless of Mylan's pricing and contrary to statutory mechanisms designed to facilitate generic competition. Even if a generic were to offer a better "net" price (*i.e.*, the price after accounting for rebates) and value for the payer and end-consumer, the Teva product would still be switched in for the generic.

18. Teva's internal documents leave no doubt as to the intent and effect of this illegal conduct. The email above, which explains why an insurer putting Copaxone on a non-preferred tier would not limit Teva's monopoly position, also explains how Teva's "House Brand" strategy contributed to this anticompetitive result. Teva's Executive Vice President for North America boasted, "**[PBM] is getting an additional rebate to fill all 'glatiramer' or Copaxone scripts with Copaxone…if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside**. **Win-win for all** . . . . **[Specialty Pharmacy] only ships brand Copaxone no matter how it is written or what the formulary states.** That is why this [putting Copaxone on non-preferred tier] has little impact." (emphasis added).

On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone...if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all...

Best regards,

<image001.png> Brendan P. O'Grady EVP and Head of North America

Highly Confidential

<image002.png>

On Jan 31, 2018, at 4:02 PM, Brendan O'Grady Highly Confidential wrote:

No as last I understood, Specialty Pharmacy only ships brand Copaxone no matter how it is written or what the formulary states. That is why this has little impact. Then again, my knowledge may be dated.

19. Teva's anticompetitive conduct, including its arrangements with PBMs and PBM-owned specialty pharmacies to exclude generic GA from formularies and dispensing, misrepresentation campaign, and illegal kickbacks, rendered Mylan's efforts to compete on price ineffective. For example, Mylan's reduction of the list price of its generic GA 40mg product by 60% in July of 2018 had hardly any impact on sales. Mylan's sales representatives reached out to customers to understand why they were unable to stimulate adoption of its generic GA product only to be told that the specialty pharmacy arm of one of the largest PBMs had a "special contract" with Teva and would not entertain any sales of generic GA, confirming that there is no price Mylan could go to that would change the equation.

20. Teva continued its strategy of abuse of the regulatory processes and court filings by filing a lawsuit against the FDA in March 2020 seeking to reclassify Copaxone as a biological product. In the suit, Teva argued that such reclassification would preclude generic GA from being automatically substitutable for Copaxone, such that generic GA, including Mylan's, would no longer be able to compete with Copaxone in the manner contemplated by the Hatch-Waxman Act and state substitution laws. Teva argued that for a generic GA product to become

substitutable again, the FDA would need to make a new determination that generic GA is "interchangeable" with Copaxone under the Biologics Price Competition and Innovation Act ("BPCIA"). As of the date of this complaint, the FDA has not made this "interchangeable" determination for any product. Thus, reclassifying Copaxone as a biological product would immediately extinguish all generic competition.

21. The district court dismissed Teva's baseless lawsuit on December 31, 2020, recognizing it as "yet another effort to stifle Copaxone competitors" after the FDA approved generic GA products (including Mylan's) "in the face of concerted resistance by Teva." As the court noted, Teva's arguments in this lawsuit ran counter to the positions it previously took. Teva's complete disregard for the merits of its arguments here underscored its anticompetitive purpose and the baseless nature of its lawsuit.

22. Teva's decade-long anticompetitive scheme, comprising multiple separately actionable anticompetitive acts, harmed competition, consumers, and Mylan. Not only did Teva's abuse of the regulatory processes and court filings significantly delay generic entry, Teva's other conduct also severely inhibited generic uptake. Consequently, consumers and payers were forced to pay at least hundreds of millions of dollars in higher costs due to Teva's supracompetitive prices for years after they should have been entitled to the benefits of lower-priced generic GA products like Mylan's.

23. Teva's anticompetitive scheme impeded Mylan's ability to compete through its lower-priced GA product. Not only was Mylan's launch delayed by Teva's abuse of the regulatory processes and court filings, Teva's other tactics also prevented Mylan from gaining the market shares normally expected in competitive markets. Teva's conduct resulted in at least hundreds of millions of dollars in lost sales. On top of monetary damages, Mylan has suffered and continues to suffer harm to its reputation and goodwill with medical professionals and MS patients throughout the country, as a result of Teva's false and misleading statements that Mylan has produced an inferior product and offers inferior support to MS patients. Teva's scheme has

thus hindered Mylan's competitive efforts and cannot be justified by any cognizable pro-competitive benefit.

24. Teva cannot justify its conduct as somehow improving competition or benefitting consumers. Teva was fully aware that its frequent price increases coupled with exclusionary tactics resulted in harm to many. For instance, in 2016, one Teva employee reported to the General Manager of Teva Neuroscience, "you can definitely see a trend in the increase in OOP [out of pocket] costs that the payers are shifting to patients and some of this may be our price increases as well."[4] The consequences even reached Teva's own employees. In one July 2018 exchange, a Teva employee explained that she could no longer afford Copaxone because she would have to pay $1,673.33 out of pocket as compared to $12 for Mylan's generic GA. Ultimately, Teva gave the employee free product, a solution unavailable to most Copaxone patients.[5]

25. Mylan seeks in this action to recover its lost profits and expenses incurred addressing Teva's conduct, damages for harm to its reputation and goodwill caused by Teva's anticompetitive and deceptive conduct; an accounting and disgorgement of Teva's ill-gotten profits from unfair competition and false advertising; an order requiring Teva to cease its unlawful conduct and engage in corrective advertising to remediate the harm it has caused to Mylan's goodwill and good reputation; and treble damages, declaratory relief, and an award of Mylan's costs and attorney's fees.

THE PARTIES

26. Plaintiff Mylan Pharmaceuticals Inc. is a West Virginia corporation, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

[4] House Teva Report, *supra* note 1, at 9. The House Teva Report also found that even Medicare patients are forced to pay high out of pocket costs. *See id.*
[5] *Id.* at 10.

27. Defendant Teva Pharmaceuticals Industries Ltd. ("Teva Ltd.") is a worldwide pharmaceutical company engaged in the development, manufacturing, marketing and sale of pharmaceutical products. Teva Ltd. is an Israeli company, having its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel.

28. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), is a Delaware corporation, having its principal place of business at 400 Interpace Parkway, #3, Parsippany, NJ 07054. Teva USA does business throughout the United States, including in this district.

29. Defendant Teva Neuroscience, Inc. ("Teva Neuro"), is a Delaware corporation, having its principal place of business at 11100 Nall Ave, Overland Park, Kansas, 66211. Teva Neuro does business throughout the United States, including in this district.

30. Defendant Teva Sales & Marketing, Inc. ("Teva S&M") is a Delaware corporation, having its principal place of business at 11100 Nall Avenue, Overland Park, Kansas 66221. Teva S&M does business throughout the United States, including in this district.

31. Upon information and belief, Teva USA controls, directs, and supervises the sales and marketing activities of Teva Neuro and Teva S&M, as well as their employees.

32. Upon information and belief, Teva Ltd. controls, directs, and supervises the sales and marketing activities of Teva USA, Teva Neuro, and Teva S&M, as well as their employees.

33. Teva USA, Teva Neuro, and Teva S&M are subsidiaries of Teva Ltd.

JURISDICTION AND VENUE

34. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. § 1331 and 15 U.S.C. § 1121(a) because this action arises under the laws of the United States, Chapter 22 of Title 15. This Court has jurisdiction over all state-law claims pursuant to 28 U.S.C. § 1367 and 28 U.S.C. § 1338(b).

35. Venue is proper in this district under 28 U.S.C. § 1391.

36. Defendant Teva Ltd. has systematic and continuous contacts with the United States. On information and belief, Teva Ltd. directs Teva USA, Teva Neuro, and Teva S&M through Teva USA at Teva USA's New Jersey headquarters regarding marketing and advertising for Teva drugs, including Copaxone. Teva Ltd. derives substantial revenue from sales in this district. Through its subsidiaries, Teva Ltd. regularly conducts business in this district.

37. Through its subsidiaries, Teva Ltd. caused harm or injury to Mylan by acts or omissions in New Jersey and this district by making false and misleading statements concerning Mylan's GA and related patient support services to doctors, nurses and patients in this district.

38. Teva USA is "at home" in New Jersey. Teva USA's principal place of business is at 400 Interpace Parkway, #3, Parsippany, NJ 07054. Teva USA markets, distributes, or sells drugs within the state of New Jersey and derives substantial revenues from those sales.

39. Teva Neuro is registered to do business in New Jersey and, based on filings with the Kansas Secretary of State, has at least one officer in New Jersey.

40. On information and belief, Teva Neuro takes direction from Teva USA as part of the below-described unlawful scheme from Teva USA's New Jersey headquarters.

41. Teva Neuro caused harm or tortious injury to Mylan by acts or omissions in New Jersey by making false and misleading statements in this district concerning Mylan's GA product and related patient support services in this district.

42. Teva Neuro has maintained systematic and continuous business contracts within the state of New Jersey and has purposefully availed itself of the benefits and protections of the laws of New Jersey.

43. On information and belief, Teva S&M takes direction from Teva USA as part of the below-described unlawful scheme from Teva USA's New Jersey headquarters.

44. Teva S&M caused harm or tortious injury by acts or omissions in New Jersey by making false and misleading statements in this district concerning Mylan's GA product and related patient support services to doctors and patients in this district.

45. Teva S&M markets, distributes, or sells drugs within the state of New Jersey, has maintained systematic and continuous business contracts within the state of New Jersey. Teva S&M has purposefully availed itself of the benefits and protections of the laws of New Jersey.

46. On information and belief, Defendants made and continue to make statements in this district concerning Mylan's GA product and related patient support services to medical professionals and patients in this district that are untrue, misleading, and harmful to Mylan.

STATEMENT OF FACTS

I. STATUTORY AND REGULATORY BACKGROUND

A. Hatch-Waxman and BPCIA Frameworks

47. The Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Restoration Act of 1984, codified at 21 U.S.C. § 355 et seq., commonly known as the "Hatch-Waxman Act," as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, codified in relevant part at 21 U.S.C. § 355 note, requires approval by the FDA before a company may market or sell a branded or generic pharmaceutical product in the United States. The overarching purpose of the Hatch-Waxman Act is to balance the preservation of brand pharmaceutical companies' incentives to innovate with the public interest in access to lower-cost, high-quality generic drugs through the creation of a carefully calibrated regulatory framework.

48. To achieve the first goal, the Hatch-Waxman Act provides for multiple types of exclusivity for brand drugs. For example, the Hatch-Waxman Act provides for a five-year exclusivity period for "new chemical entities," *i.e.*, where the active pharmaceutical ingredient has not been previously approved for any other drug. 21 U.S.C. § 355(c)(3)(E)(ii).

49. To achieve the second goal of "get[ting] generic drugs into the hands of patients at reasonable prices – fast," *Andrx. Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C.

Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)), the Hatch-Waxman Act creates a procedure for generic manufacturers to file ANDAs with the FDA. An ANDA filer need not conduct full clinical trials, as is required for a New Drug Application ("NDA"). Instead, an ANDA filer only has to show that its drug is bioequivalent to the "reference listed drug," typically the brand drug, to demonstrate that the generic product has the same or comparable safety and efficacy as the reference listed drug.

50. Under the Hatch-Waxman Act, NDA holders are required to identify all patents covering the brand drug and such patents' expiration dates in an FDA publication referred to as the "Orange Book." 21 U.S.C. § 355(b)(1) and (c)(2). If an ANDA applicant seeks FDA approval to sell a generic drug before the expiration of the patents listed in the Orange Book as covering the drug, the ANDA must contain a certification that each of the relevant patents "is invalid or will not be infringed." 12 U.S.C. § 355(j)(2)(A)(vii)(IV). Such a certification is known as a "Paragraph IV Certification."

51. In accordance with the Hatch-Waxman framework, the FDA assigns therapeutic equivalence codes to pharmaceutically equivalent drug products. A drug product is deemed to be therapeutically equivalent (A-rated) only if the FDA determines that the product is fully interchangeable with the reference product. The FDA classifies as therapeutically equivalent, and thus substitutable, those products that are (1) approved as safe and effective, (2) pharmaceutically equivalent (which means, in part, drug products in identical dosage forms that contain identical amounts of the identical active ingredient, and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency (21 C.F.R. § 320.1(c)), (3) bioequivalent, (4) adequately labeled, and (5) manufactured in compliance with Current Good Manufacturing Practice regulations.

52. In many states, pharmacies are required by "automatic substitution" laws to substitute A-rated generic drugs for brand drugs even if the prescription specifies the brand drug. In states where substitution is not mandated, pharmacies may choose to substitute generics to

save costs. Generic drugs that are not A-rated to the reference listed brand drug cannot be automatically substituted for the reference listed brand drug at the pharmacy level.

53. An exception to the automatic substitution requirement applies in most states if the prescriber indicates that the prescription should be DAW or its state-specific equivalent. *See, e.g.*, 35 P.S. § 960.3(a) ("Whenever a pharmacist receives a prescription for a brand name drug, the pharmacist shall substitute a less expensive generically equivalent drug unless requested otherwise by the purchaser or indicated otherwise by the prescriber.").

54. In addition to pharmaceutical products, which are regulated under the Hatch-Waxman framework, the FDA also regulates biological products. Similar to the Hatch-Waxman Act, the Patient Protection and Affordable Care Act amends the Public Health Service Act ("PHSA") to create an abbreviated pathway for manufacturers to obtain FDA approval for biological products that are demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-approved biological product. 42 U.S.C. § 262(k)(2). These new statutory provisions are commonly known as the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").

55. Manufacturers of biological products (*i.e.*, biologics) submit Biologics License Applications ("BLAs") to the FDA for approval of the products covered by the PHSA, including products for which approval is sought based on biosimilarity or interchangeability with an already-approved biological product. 42 U.S.C. § 262(a). Following the amendments to the definition of "biological product," the FDA has reclassified some NDAs filed under the Hatch-Waxman Act as BLAs, which means the drugs for which these NDAs were filed were reclassified as biologics. The reclassification took effect on March 23, 2020.

56. The Hatch-Waxman and BPCIA frameworks have important differences that may impact how a drug is made available to patients. A generic drug approved under the Hatch-Waxman Act generally can be substituted for the corresponding brand drug, and often is automatically substituted for the brand drug at pharmacies under state laws. In contrast, under BPCIA, while an approved biosimilar can be prescribed, it cannot be substituted for the

corresponding biologic "without the intervention of the health care provider who prescribed" the biologic, unless the FDA takes the further step of deeming the biosimilar to be "interchangeable." *See* 42 U.S.C. § 262(i)(3). To date, the FDA has not determined any biosimilar to be "interchangeable" with a biologic.

B. Benefits of Generic Competition

57. Generic drugs typically are sold at substantial discounts from the price of the brand drug. As additional generic companies enter the market, these later entrants drive down prices further, hoping to take market share from earlier generic entrants by competing on price. Generic drugs prices can fall to as low as five percent of the brand drug's price in some circumstances. A 2017 study commissioned by the Association for Accessible Medicines ("AAM") found that while brand drug prices generally increased by over 200% between 2008 and 2016, generic drug prices generally decreased by approximately 75% during this period.

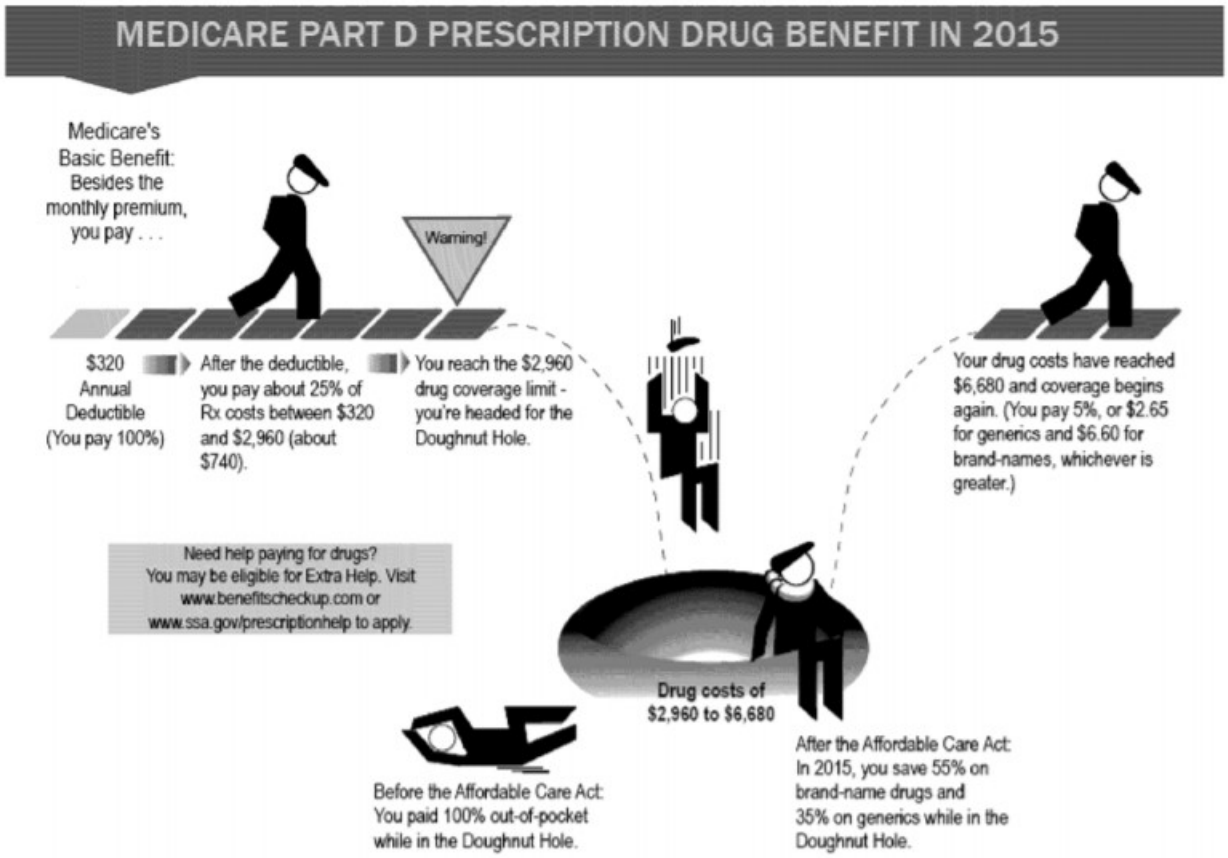
58. Generic drug competition generates large savings for consumers and federal, state, and private payers. "Payers" include health plans and pharmacy benefit managers. A 2004 FDA study found that consumers whose needs can be fully satisfied with generic drugs could enjoy reductions of 52% in their daily medication costs. More recently, the 2017 AAM study found that generic drugs generated savings of $1.67 trillion for the U.S. health care system between 2007 and 2016.

59. Generic savings have steadily increased from $8-10 billion in 1994, as found by a 1998 Congressional Budget Office Report, to $253 billion in 2016, as found by the 2017 AAM study. Within the $253 billion in savings from generic drugs in 2016, Medicaid savings constituted $37.9 billion, and Medicare savings constituted $77 billion. The 2017 study also cites IMS data showing that generic drugs account for 89% of prescriptions, but only 26% of costs. Similarly, a 2016 Report to Congress on "Prescription Drugs: Innovation, Spending, and Patient Access" from the U.S. Department of Health and Human Services unequivocally states: "Generic

drugs account for the majority of dispensed prescriptions, but a relatively small percentage of spending."

C. Anti-Kickback Statute and Medicare Part D

60. Medicare, including Medicare Part D, is a "Federal health care program" under the federal anti-kickback statute ("AKS"). *See* 42 U.S.C. §§ 1320a-7b(b)(2), 1320a-7b(f). Under the Medicare Part D program, Medicare contracts with private entities (Part D plan sponsors or "PDP sponsors") to administer prescription drug plans. Patients enrolled in Medicare Part D plans must pay a portion of the drug at the time of purchase, *i.e.*, the copay; the PDP sponsor pays the rest of the purchase price and is then reimbursed by Medicare. Generally, after the Medicare Part D beneficiary's copayment reaches an initial coverage limit, the beneficiary enters a coverage gap, colloquially known as the "donut hole." During the coverage gap, the copayment obligations increase substantially until the beneficiary's payments reach the annual out-of-pocket threshold. At that point, the beneficiary enters "catastrophic coverage," where copay is the greater of: (i) a small fixed dollar amount (originally $5 for brand drugs in 2006, which increases slightly each year); or (ii) 5% of the prescription drug costs. 42 U.S.C. § 1395w-102(b)(4)(A). In practice, the copay during catastrophic coverage for any expensive brand drug is 5% of the cost of the drug. Medicare and the PDP sponsor cover the remainder of the drug cost.



61. One of the purposes of the AKS is to guard against the risk of overutilization, increased costs, and poor quality, of health care goods and services reimbursed by the federal government by preventing payments to those who can influence health care decisions. As the Office of Inspector General for the Department of Health and Human Services noted, pharmaceutical manufacturers' patient assistance programs that subsidize the copayment of Medicare Part D beneficiaries "would be squarely prohibited by the [AKS] statute, because the manufacturer would be giving something of value (i.e., the subsidy) to beneficiaries to use its product." Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005). One of the risks associated with such a subsidy is that it would reduce "beneficiaries' incentives to locate and use less expensive, equally effective drugs" and "eliminat[e] a market safeguard against inflated prices." *Id.*at 70625-26. Further, while manufacturers may lawfully donate to independent, *bona fide* charities that then provide

assistance to patients, "the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." *Id.* at 70627.

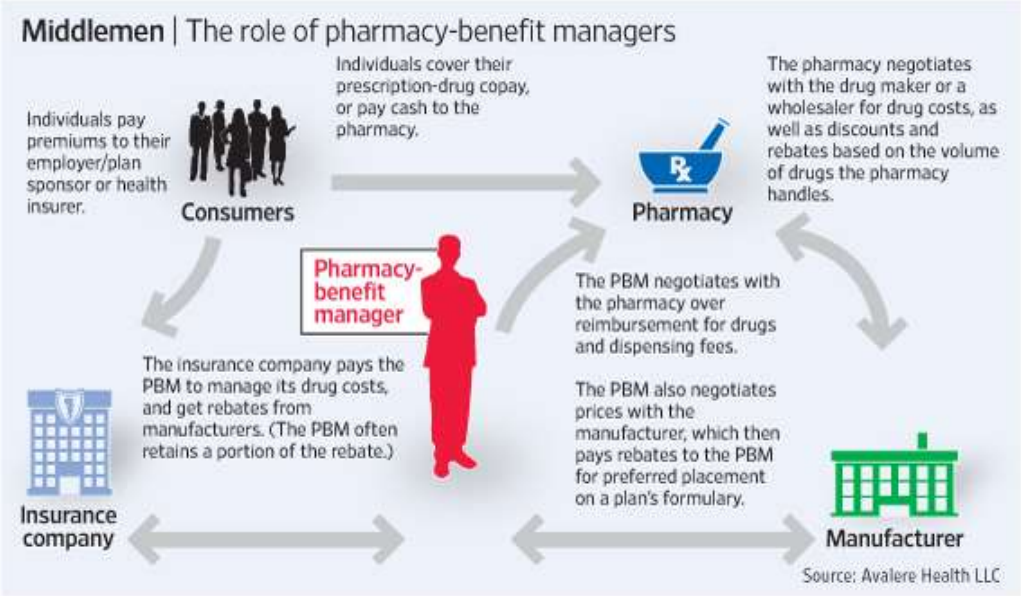
II. THE ROLE OF PBMS AND SPECIALTY PHARMACIES IN THE PHARMACEUTICAL SUPPLY CHAIN

62. Pharmacy Benefit Managers, or PBMs, reside in the middle of the pharmaceutical supply chain. PBMs are service providers that manage prescription drug benefits on behalf of their payer/plan sponsor clientele (health insurance companies, self-funded health plans, large companies, government entities, etc.).

63. In theory, a PBM might aggregate the purchasing power of its payer clients and leverage the aggregated purchasing power to extract concessions from drug manufacturers in the form of reduced prices. In addition, PBMs create pharmacy networks and negotiate terms for reimbursement to pharmacies. Many PBMs also either own mail order and specialty pharmacies or share common ownership with mail order and specialty pharmacies.

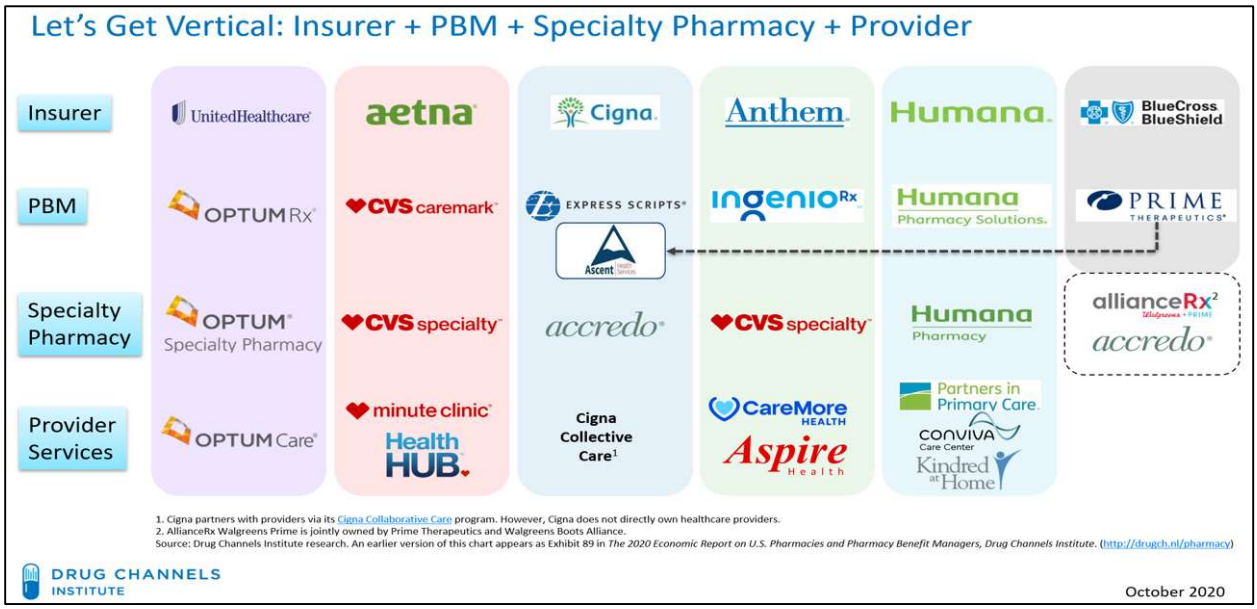
64. PBMs also create drug "formularies" for their health plan clients. A drug formulary is industry jargon for a list of prescription drugs for which the health plan will reimburse pharmacies on behalf of the plan's members. If a drug is not included on a formulary, the health plan generally will not cover it. If a doctor prescribes a drug to a patient that is not on the formulary, the patient must generally pay the entire cost of the drug out-of-pocket. The creation and leveraging of formularies create a method by which PBMs can steer payer – and therefore ultimately prescriber – decisions.

65. The following graphic illustrates the PBMs' position in the pharmaceutical supply chain:



66. In brand-vs.-brand scenarios, competition often occurs at the formulary level. Brand manufacturers will compete for preferred and even exclusive placement on PBMs' formularies and may offer a host of concessions to obtain such placement, including price reductions, rebates, and temporal commitments. This form of competition may be contrasted with brand-vs.-generic competition, in which generic manufacturers have significantly less leverage to compete with the brand manufacturer. Indeed, it is this awareness of brands' ability to preempt adoption of generic competitors that has compelled many states to introduce automatic substitution laws, which require the generic drug to be automatically substituted for the corresponding brand drug at the pharmacy level.

67. A small number of PBMs control the vast majority of the PBM market segment. Specifically, the top four PBMs account for over 75% market share. Five of the six largest specialty pharmacies are also aligned with the largest PBMs: CVS Specialty / Caremark (both owned by CVS); Accredo / Express Scripts (Accredo was a subsidiary of Express Scripts during much of the relevant time period; they are now both owned by Cigna); Alliance Rx Walgreens Prime and Accredo (aligned with Prime, PBM arm of the Blue Cross Blue Shield system); Optum Specialty Pharmacy / OptumRx (both owned by UnitedHealth); and Humana Specialty Pharmacy (owned by Humana, which owns its own PBM).



III. COPAXONE

68. Teva distributes and sells Copaxone throughout the United States, including in New Jersey and this district. Teva USA holds NDA No. 20-622 for Copaxone in 20 and 40mg strengths. Copaxone is indicated as a disease-modifying therapy for the treatment of patients with relapsing forms of MS, including the reduction of the frequency of relapses in relapsing-remitting MS ("RRMS"). RRMS is manifested by relapses and slow progression of the disease that can affect the functioning of multiple systems. The majority of MS patients have RRMS.

Disease-modifying therapies alter the course of the disease and prevent flare-ups, and are distinguished from other treatments of MS, such as treatment of flares and symptom control therapies.

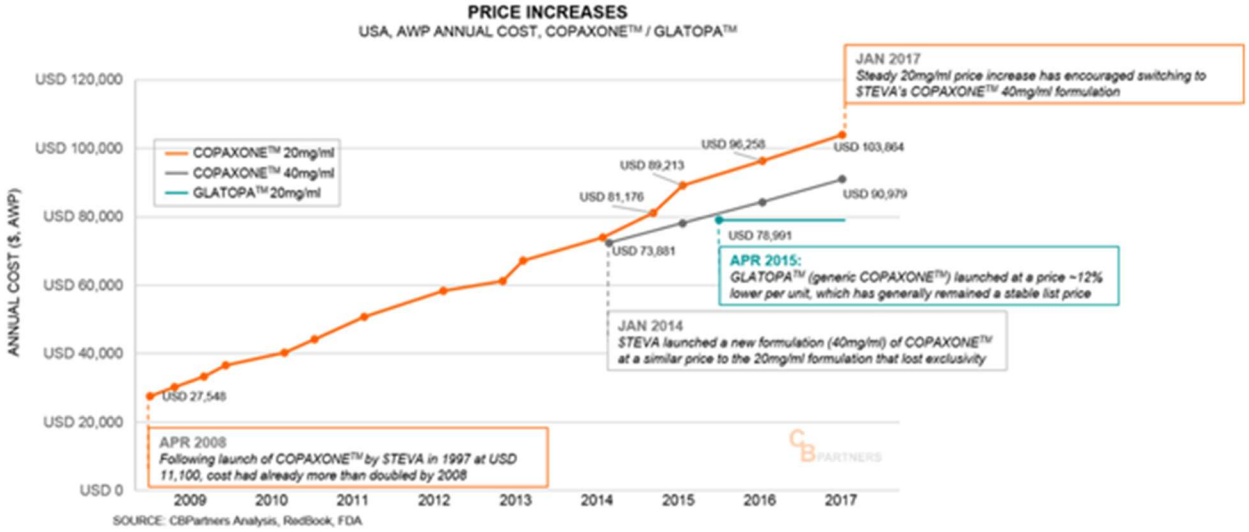
69. MS is the most common cause of neurological disability in young adults and affects more than 2.5 million people worldwide. In the United States, there are approximately 900,000 total MS patients as of 2019. Individuals suffering from MS have a wide variety of symptoms including extreme fatigue, mobility problems, vision problems, and weakness.

70. Most people with MS are diagnosed between the ages of 20 and 50, although individuals as young as 2 and as old as 75 have developed it. MS is incurable. Copaxone is prescribed by neurologists and other medical professionals who treat MS. There are approximately 11,000 medical professionals who have prescribed Copaxone.

71. In addition to selling the Copaxone drug, Teva has provided certain patient support services through its "Shared Solutions" patient hub. The Shared Solutions hub has provided, among other things, nurse training and education support as well as copay support to patients taking Copaxone.

72. Due to the lack of generic competition, Teva has been able to raise the price of Copaxone astronomically since launch, even though newer therapies for MS have become available. When Teva first launched Copaxone 20mg/vial in 1996, the annual average wholesale price ("AWP") was approximately $8,292. In 2017, the AWP of Copaxone 20mg annually was approximately $91,401 (*i.e.*, a 1002% price increase).[6] When Teva first launched Copaxone 40mg in 2014, its annual AWP was $63,000. In 2017, the annual AWP of Copaxone 40mg was approximately $80,000.

[6] *See also* House Teva Report, *supra* note 1, at 1 ("Since launching Copaxone 20 mg/ml, Teva has raised the price of the drug 27 times.").



IV. COPAXONE APPROVAL HISTORY

73. Teva has sold Copaxone in the United States for more than 20 years, mostly without any generic competition. The FDA first approved Copaxone as a 20 mg/vial product "for solution" on December 20, 1996. The FDA approved the use of Copaxone 20mg pre-filled syringes for injectable use on February 12, 2002. The Copaxone 20mg injectable product requires daily dosing.

74. On January 28, 2014, the FDA approved Copaxone 40mg in a pre-filled syringe for injection to be administered three times per week. Starting around that time, Teva launched a campaign to encourage its Copaxone customers to switch to the 40mg strength where Teva believed it had patent protection from generic competition. The 40mg strength was also subject to regulatory exclusivity that expired on January 28, 2017.

V. GENERIC GA APPROVAL HISTORY

A. Sandoz

75. Sandoz filed ANDA No. 090218 for generic GA 20mg on December 27, 2007 and sent a Paragraph IV notice to Teva on or about July 10, 2008. The FDA approved Sandoz's ANDA on April 16, 2015.

76. Sandoz's product, marketed as Glatopa®, was the first generic GA product in the 20mg strength.

B. Mylan

77. Mylan engaged in extensive preparatory work for the launch of its generic GA product and invested tens of millions of dollars to bring it to market. Mylan entered into an agreement with Natco Pharma Ltd. for the production of GA. Then, for years, Mylan worked to get FDA approval and fought to defend itself from Teva's numerous lawsuits and anticompetitive practices.

78. Mylan filed ANDA No. 091646 for generic GA 20mg on June 29, 2009 and sent a Paragraph IV notice to Teva on September 16, 2009. Mylan submitted its application for 40mg GA to the FDA on February 12, 2014 and sent a Paragraph IV notice to Teva on or about August 28, 2014.

79. On or about October 3, 2017, the FDA granted final approval to Mylan's generic GA 20mg and 40mg products. Specifically, after concluding its review, the FDA determined that Mylan's GA is an "AP" rated generic equivalent of Copaxone. The FDA's Approval Letter for the 40mg product states in part: "We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved, effective on the date of this letter. The Office of Bioequivalence has determined your Glatiramer Acetate Injection, 40 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Copaxone® Injection, 40 mg/mL, of Teva Pharmaceuticals USA (Teva)." The approval letter for Mylan's 20mg product contains identical language.

80. Shortly after the FDA approved Mylan's generic GA, Mylan launched in the United States the first generic GA 40mg for 3-times-a-week injection that is a therapeutically equivalent, substitutable generic version of Teva's Copaxone 40mg formulation. Mylan also launched the 20mg product as the second bioequivalent generic GA 20mg product on market.

VI. MYLAN'S CONSIDERABLE EFFORTS TO SUPPORT ITS GENERIC GA

81. In the immediate run-up to release, Mylan developed a website for its GA products and for its hub for patient support services, Mylan MS Advocate (subsequently renamed Mylan Advocate). All patients prescribed and taking Mylan's GA are eligible to enroll in the hub, which provides numerous patient services, including copay support that reduces out-of-pocket costs of qualifying patients (sometimes to $0), trained Benefits Advocates who help patients with their insurance benefits and with finding other sources of financial assistance, and nursing support to help teach patients how to use an injectable medication.

82. GA copays tend to be higher than for many other medications. Thus, copay support is important for MS patients taking GA, either branded Copaxone or a generic GA product.

83. Mylan MS Advocate patient support also includes nurses who are available by phone 24 hours per day, 7 days per week. The nurses talk to patients about their condition and Mylan's GA to provide injection training and educational support upon request. Nurses also provide tips on preparing, storing, and disposing of GA and help connect patients with local and online MS communities. In addition to the above services, Mylan also provides Mylan Smart Injection Tracker, an interactive smartphone app that helps patients track and plan their injections.

84. Patient training and nursing support services are important for MS patients taking GA injections, either Copaxone or a generic GA injectable product. MS patients taking GA require significant training and nursing support services because GA is an injectable product

that requires training to administer properly. Improper administration can lead to injection site reactions and significant discomfort for patients.

VII. IMPORTANCE OF COPAXONE BUSINESS TO TEVA

85. Copaxone is by far Teva's best-selling product in the United States and worldwide, and has been for many years. Sales of Copaxone have generated Teva more than $40 billion in revenue globally—including more than $30 billion from the United States alone.

86. In 2016 alone, Copaxone accounted for $4.2 billion in revenue (including $3.5 billion in the United States), or 19% of Teva's global revenues. In the United States, Copaxone accounted for nearly 30% of Teva's revenue in 2016. In 2017, even when faced with one calendar quarter of generic competition in the 40mg segment, according to Teva's SEC reporting, Copaxone still represented approximately 17% of Teva's revenue worldwide and approximately 25% of its revenue in the United States.

87. Copaxone's importance to Teva's viability as a company cannot be overstated. Perhaps reflecting Teva's concern about Copaxone's position, Teva was forced to settle claims that it bribed government officials and medical professionals in Russia, Ukraine, and Mexico to increase sales of Copaxone, resulting in guilty pleas and nearly $520 million in criminal and civil fines in the United States—the largest criminal fine imposed against a pharmaceutical company for violations of the Foreign Corrupt Practices Act. In February 2017, Teva's then CEO Erez Vigodman stepped down amid an Israeli investigation into Teva's bribery scandals.

88. In 2017, Teva wrote in SEC filings that it "rel[ies] heavily on the continued absence of a generic version of our 40 mg/mL, three-times-a-week version of Copaxone®." Teva Pharmaceutical Industries Limited, Annual Report (Form 20-F) (Feb. 15, 2017), at 1. Teva explained that "one of the key elements" of its business strategy was "[m]aintaining Copaxone®." *Id.* at 23.

89. Media and analysts have criticized Teva for being over-reliant on revenue generated by Copaxone. In 2014, a Goldman Sachs analyst warned: "As we approach the

potential entry of Copaxone generics, we grow increasingly concerned about Teva's dependence on Copaxone to compensate for challenges in other business areas." One year earlier, a column in the Israeli newspaper *Ha'aretz* called the expiration of Teva's Copaxone patents a "ticking time bomb," noting that Teva had thus far "fail[ed] to deal with [its] dependence" on Copaxone and that that failure was "the story of Teva's downfall: from a growth company in which every private and institutional investor wants to hold shares, to one where 5,000 global employees will lose their jobs in the first, and not necessarily final, round of layoffs."

90. Teva projected that Mylan's launch of generic GA would have an impact on earnings of about $0.30 per share in 2017. Additionally, Teva admitted in a court filing that it "stands to lose hundreds of millions of dollars *within* months of FDA approving the launch of a putative generic version of Copaxone®" (emphasis in original). It later emphasized that "[m]ore than a billion dollars are at stake" in the first year of generic entry alone.

91. Given the importance of Copaxone to Teva, it is no surprise that Teva "planned for the eventual introduction of a generic competitor." Teva Pharmaceutical Industries Limited, Report of Foreign Private Issuer (Ex. 99-1 to Form 6-K) (Oct. 4, 2017). Indeed, Teva has spent millions of dollars fighting and delaying the launch of generic GA, and many more millions of dollars to impede generic uptake when generic GA eventually was approved.

VIII. TEVA'S GLOBAL CAMPAIGN TO INSULATE COPAXONE FROM GENERIC COMPETITION

92. It is important to place Teva's anticompetitive scheme in the United States in the context of Teva's worldwide campaign to delay and prevent generic competition to Copaxone. While the vast majority of Teva's sales for Copaxone comes from the United States and less than 20% of Copaxone sales came from abroad as of 2016, Teva has implemented a worldwide scheme consistent with its U.S. strategies to insulate even those foreign sales from competition. In fact, Teva's global scheme largely parallels its plethora of anticompetitive conduct in the United States.

93. For example, Teva's tactics in Europe were very similar to the strategy Teva has been using in the United States. Specifically, Teva's anticompetitive scheme in Europe includes: (i) filing pan-European sham patent litigations, in combination with interim injunction applications; (ii) filing serial meritless regulatory challenges to national marketing authorizations; (iii) filing and timing secondary patent clusters to delay generic entrants; (iv) making misleading representations to national patent authorities to extend supplementary protection certificate ("SPC") durations for Copaxone; (v) timing the shifting of the market to the 40mg product in each member state to impede generic competition; and (vi) making misrepresentations regarding generic competitors, including to facilitate the equivalent of a DAW prescription. These efforts even extend to Teva's attempts to use European courts as a means of delaying generic entry in the United States, such as Teva's attempt to use an Irish court to enjoin Mylan from manufacturing generic product in Ireland for sale in the United States—a suit that Mylan defeated in June 2018.

94. First, Teva initiated approximately 40 intellectual property proceedings throughout at least 17 European Union ("EU") member states. In the majority of countries in which Teva has commenced patent litigation, it has sought preliminary injunctions to prevent generic entry. These litigations' lack of merit is shown by, amongst other factors, Teva's allegation of infringement of claims that *have already been struck down* by the European Patent Office and in other member states. Further, Teva also filed lawsuits in foreign jurisdictions to seek to prevent the sale of generic GA *in the United States*. Specifically, Teva sought an injunction against Mylan in the Irish courts and requested an order that Mylan destroy its stock of generic GA for export to the United States and be barred from producing more product during the pendency of the litigation. In June 2018, the High Court of Ireland denied Teva's request for an injunction and refused to order Mylan to destroy any product, pointing in part to the fact that there was no legal or regulatory bar to other generics appearing on the U.S. market at any time.

95. Second, Teva filed serial meritless regulatory challenges to national marketing authorizations to prevent generic competition. Specifically, Teva has filed at least thirteen such

challenges in ten EU member states regarding generic GA 20mg. Except for the challenges that Teva withdrew, all of its challenges were rejected. Further, after its legal regulatory arguments relating to the 20mg generic product were rejected by all the national health authorities and courts concerned, Teva still persisted in raising the same failed legal arguments regarding the 40mg generic product before a number of national health authorities. It should have been obvious to Teva that its legal arguments were meritless, and this repeated conduct demonstrates that Teva's regulatory challenges were merely for the purpose of preventing competition from generic GA 20mg and 40mg.

96. Third, Teva filed successive divisional patent applications to prolong the period of uncertainty for generic entrants, because invalidation of a parent patent does not ensure certainty when divisional patents are still in force. Teva timed these divisional patent applications so that in each patent family, there would always be some divisional patents in force over time. Additionally, Teva sought to prevent the review of these divisional patents on the merits to prolong its patent clusters, including by causing the revocation of divisional patents just before a ruling on the merits by the Technical Board of Appeal of the European Patent Office to avoid a negative substantive ruling. Moreover, when Teva's patents were subject to challenge before the U.S. Patent and Trademark Office or the European Patent Office, it attempted to defend those patents by making statements that directly contradicted the statements Teva made to the U.S. FDA. In particular, when Teva's patents for the 40mg strength were challenged for obviousness, Teva sought to discredit the very studies and data that it relied on in its supplemental NDA ("sNDA") filed with the FDA seeking regulatory approval of the 40mg strength in the United States.

97. Fourth, Teva made misleading representations to national authorities to extend SPCs for Copaxone beyond what Teva was entitled to. SPCs operate in a similar manner to the patent term restoration portion of the Hatch-Waxman Act, and grant additional protection to a drug based on the date of filing the patent application and the date of the first market authorization for the product in the European Community. In applying for the SPCs, Teva made

misleading representations as to Copaxone's first date of market authorization, and the SPCs were granted (even though they should not have been). Accordingly, Teva obtained the SPCs through misrepresentations before the patent agencies.

98. Fifth, in each EU member state, when faced with the expiry of the 20mg patents, Teva timed the introduction of the 40mg product, on which it faced no generic competition, to be just before the date of generic entry, even though Teva's 40mg product received marketing authorization. Further, Teva took additional steps to shift the market to 40mg, over and beyond any shift resulting from the attributes specific to the 40mg product alone. Specifically, Teva undertook promotional efforts aimed at prescribers and patients, as well as priced the 40mg product at or below the 20mg price, including offering disproportionate rebates for the 40mg and waiving copay for the 40mg product in certain countries. As described below, in the United States, Teva went even further and employed several other anticompetitive tactics to ensure that the market shift from 20mg to 40mg was sufficient to neutralize generic competition.

99. Finally, Teva engaged in a misrepresentation campaign to prevent generic uptake. In particular, Teva made express or implied statements to national health authorities, medical professionals, and patients to the effect that generic GA is somehow less effective than branded Copaxone because of the complex nature of the active ingredient, and that generic GA "should not be considered substitutable with COPAXONE." These statements are false because the competent national authorities, in granting marketing authorizations to generic GA, affirmed the efficacy and therapeutic equivalence of the generic product. For example, the Dutch health agency determined: "Based on all data presented, […] [the generic GA product] can be regarded as therapeutic equivalent to the reference product. 'Therapeutical equivalence' means that the efficacy and safety of this hybrid formulation is similar to the efficacy and safety of the reference product." As the Dutch agency noted, the other EU member states agreed with this conclusion. Despite their clear falsity, Teva used these misrepresentations to encourage physicians to prescribe Copaxone with the equivalent of DAW annotations to prevent generic substitution in

EU member states that mandate or allow automatic generic substitution, similar to many U.S. states.

100. Accordingly, Teva's course of conduct in Europe and worldwide closely mirrors its campaign against generic GA in the United States and demonstrates a pervasive, global anticompetitive scheme to protect its Copaxone franchise against generic competition. On March 4, 2021, the European Commission announced that it had opened "a formal antitrust investigation to assess whether the pharmaceutical company Teva has illegally delayed the market entry and uptake of medicines that compete with its blockbuster multiple sclerosis drug Copaxone."[7] The investigation will focus on (i) "whether, following the patent expiry, Teva may have artificially extended the market exclusivity of Copaxone by strategically filing and withdrawing divisional patents, repeatedly delaying entry of its generic competitor who was obliged to file a new legal challenge each time"; and (ii) "whether Teva may have pursued a communication campaign to unduly hinder the use of competing glatiramer acetate products. The Commission has indications that Teva's campaign, primarily directed at healthcare institutions and professionals, may have targeted competing products to create a false perception of health risks associated with their use, even following the approval of these medicines by competent public health authorities." The Commission noted that "[i]f proven, Teva's behaviour may amount to an abuse of dominant position and infringe Article 102 of the Treaty on the Functioning of the European Union (TFEU) and Article 54 of the European Economic Area (EEA) Agreement."

IX. TEVA'S DECADE-LONG CAMPAIGN TO BLOCK COMPETITION FROM GENERIC GA IN THE UNITED STATES

101. In the United States, Teva's anticompetitive scheme to delay and block generic competition to Copaxone has passed its ten-year anniversary and is still going strong. This

[7] European Commission, *Antitrust: Commission opens formal investigation into possible anticompetitive conduct of Teva in relation to a blockbuster multiple sclerosis medicine*, Press Release (Mar. 4, 2021), https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1022.

anticompetitive scheme continues through the present day, with the latest tactic taking the form of a baseless lawsuit against the FDA to seek reclassification of Copaxone as a biologic, which a district court recently recognized as "yet another effort to stifle Copaxone competitors." In between, several of Teva's other anticompetitive acts, timed to have the maximum impact on generic competition, also continue today. These tactics were and are designed both to delay the launch of generic GA and to eliminate the competitive effectiveness of that launch. As discussed above, they include:

- Abusing the regulatory processes before the FDA and court filings to delay generic entry;
- Shifting the market to 40mg through economically irrational pricing, and anticompetitive agreements and tying;
- Engaging in a campaign of misrepresentations regarding generic GA to increase DAW prescriptions;
- Entering into "House Brand" agreements with PBMs and PBM-owned specialty pharmacies whereby Teva conditioned any and all rebates on complete exclusion of generic GA from formularies, and PBM-owned specialty pharmacies would prevent the dispensing of generic GA regardless of the prescription and even if the generic GA was on formulary; and
- Using illegal kickbacks to diminish the effectiveness of generic competition.

102. First, since at least 2008, Teva implemented a repetitive and continuous strategy to abuse regulatory and judicial processes to delay the launch of generic GA. As explained below, Teva has continually pursued this strategy, most recently via a baseless lawsuit against the FDA that Teva filed last year seeking to reclassify Copaxone as a biological product.

103. Second, when Teva learned that Sandoz had applied for FDA approval of a generic GA 20mg that would compete with Teva's 20mg Copaxone product, it sought to block and delay the competitive impact of Sandoz's launch by switching the market to the new ostensibly patent-protected 40mg strength. Indeed, not only did Teva price this allegedly improved formulation *lower* than its existing 20mg formulation to drive patients away from the

20mg product that was facing generic entry—a pricing strategy whose only rationale was to harm competition—it went even further and tied rebates on the 20mg product to adding 40mg to formularies while also entering into agreements with PBMs to switch doctors to the 40mg product. Teva's strategy of shifting the market to 40mg was so effective that Sandoz's launch of its 20mg generic GA formulation gained minimal sales and delivered little to no competitive benefits to patients.

104. While the market switching continued, Teva learned of Mylan's application for FDA approval of a generic 40mg GA product. It then sued Mylan for patent infringement regarding the 40mg formulation, which imposed an automatic 30-month stay on FDA approval of Mylan's application. Teva's effort to assert its 40mg three-times-a-week patents met with defeat across the board. The district court found all of Teva's 40mg patents obvious. Three separate *inter partes* review proceedings before the PTAB found the patents unpatentable. And all of the district court and PTAB decisions were affirmed by the Federal Circuit. In unsuccessfully prosecuting the 40mg litigations, Teva denigrated its own prior art patent applications, attempted to discredit prior art clinical trials (many of which were Teva's own work), and presented arguments directly conflicting with earlier representations Teva made to the FDA to explain the rationale for its reduced frequency GA dose regimen. Ultimately, every tribunal to review Teva's 40mg three-times-a-week patents found the dosage regimen obvious over the prior art. The district court recognized Teva's 40mg three-times-a-week patents for exactly what they were: "nothing more than 'life-cycle management'- an attempt to continue to monopolize a multi-billion dollar market for a blockbuster drug."

105. Third, in preparation for Mylan's anticipated launch in late 2017, Teva ramped up its campaign to increase DAW prescriptions targeting the 40mg product in mid-2017. In addition to a variety of marketing tactics, including through the use of Teva's patient support portal, Teva systematically disparaged Mylan's generic GA product through a series of false and misleading material statements that substantially impeded the uptake of Mylan's product at launch. Such practices continue to harm Mylan's sales and reputation as the campaign continues.

Among other false and misleading statements, Teva has falsely represented that Mylan's product is less effective than branded Copaxone, Mylan lacks a copay assistance program, and Mylan does not offer patients nursing support. Each of these statements is untrue, and Teva was aware that they were untrue at all times. These false, misleading, and deceptive statements have caused health care providers and patients to avoid Mylan's generic GA product, impeded automatic substitution, and substantially reduced Mylan's sales. While Mylan, as a generic manufacturer, does not ordinarily market its generic drugs through sales representatives,[8] it tried to correct Teva's misrepresentations by having company representatives communicate with health care providers. However, Mylan's efforts to revive its reputation were thwarted because a large number of providers already believed Teva's lies and refused to even talk to the Mylan representatives or argued with them using the arguments they heard from Teva.

106. Fourth, about the same time that Teva ramped up its misrepresentation campaign, it also began entering into "House Brand" agreements with the key PBMs and PBM-owned specialty pharmacies to foreclose uptake of Mylan's generic GA product. In particular, Teva went beyond ordinary competition for PBM formularies and adopted an all-or-nothing approach, where it refused to pay rebates at all unless generic GA was excluded from formulary. Thus, Teva's agreements with PBMs prevent them from putting generic GA on their formularies at all, such that the use of generic GA would not be covered by insurance.

107. As part of its arrangements with the PBMs, Teva and the PBM-owned specialty pharmacies also agreed not to dispense generic GA at the pharmacy *even if the prescription specifies generic GA*. Instead, the pharmacies would dispense branded Copaxone regardless of the prescription, which completely blocks generic GA from reaching consumers. Teva's

[8] In a competitive market, generic manufacturers can often rely on automatic substitution laws and other price control mechanisms by payers, such as insurance tier management, to compete with brand drugs. Not having to maintain a large salesforce allows generic manufacturers to keep costs low and pass savings on to payers and consumers. This is precisely how competition is supposed to function under the Hatch-Waxman Act and state substitution laws.

agreements with the specialty pharmacies and PBMs to limit generic substitution are in stark contrast with traditional brand-vs.-brand formulary competition.

108. The effects of the misrepresentation campaign and Teva's agreements with PBMs and PBM-owned specialty pharmacies feed into and amplify each other, making them especially effective in preempting Mylan's launch, and subsequently continue to impede the sale of Mylan's generic product. As evidence of the effectiveness of Teva's combined anticompetitive tactics, even Mylan's direct attempt to compete on price by cutting the list price of its GA 40mg by 60% had hardly any impact on sales, when a similar price reduction by a generic in a competitive market would ordinarily result in significant switching by customers from the brand drug to the generic drug.

109. Moreover, Teva supported these anticompetitive tactics with its decade-long use of illegal kickbacks to third-party foundations to gain sales for the brand product, and subsequently to keep sales on the brand product even when generic GA had become available. For several years, Teva has been subsidizing Medicare Part D patients' copay with purported "donations" to third-party foundations, even though the prices of GA—and the corresponding copay obligations—would have been much more affordable absent Teva's anticompetitive conduct to extend its monopoly. These "investments" kept patients on Copaxone and generated sales for Teva. Then, when generic GA came onto the market, Teva used these illegal kickbacks to remove patients' and doctors' incentives to use the generic drug, even if the payer, such as an insurance carrier or Medicare, sought to promote generic drug use by putting it on the preferred tier. Teva's conduct raised and continues to raise costs of the health care system, as payers and the government are forced to pay the unsubsidized and supracompetitive price of Copaxone instead of lower-priced generic GA, and may pass on a portion of this overcharge to consumers. Thus, Teva's decade-long "investments" have become a tool to further the effectiveness of its anticompetitive strategy.

110. Finally, just as generic GA started to gain limited market shares (which were still nowhere near the level of generic conversion ordinarily expected but for anticompetitive

conduct), Teva returned to its strategy of abusing regulatory processes and court filings. Specifically, Teva asked the FDA to reclassify Copaxone as a biologic under the PHSA, rather than as a drug under the Hatch-Waxman Act's ANDA framework. Teva hoped this strategy would cause generic GA to no longer be automatically substitutable for Copaxone even though nothing about the drug products themselves had changed. In making this reclassification request, Teva made arguments that directly contradicted and were wholly inconsistent with previous positions it had taken in Citizen Petitions requesting the FDA not to approve GA ANDAs.

111. When the FDA refused to grant Teva's anticompetitive request, Teva sued the FDA in federal court. Teva's newest lawsuit, had it been successful, would have completely eliminated any current generic competition to Copaxone for at least the near future. However, Teva's baseless lawsuit was dismissed in December 2020 in an opinion that specifically called out the hypocrisy of Teva's self-contradictory arguments. Ultimately, the district court recognized Teva's lawsuit as "yet another effort to stifle Copaxone competitors."

A. Teva's Shifting of the Market to 40mg Through Economically Irrational Pricing and Anticompetitive Agreements

112. In July 2008, Teva received a Paragraph IV certification from Sandoz, which confirmed that the company had filed an ANDA for 20mg GA. Rather than allow the Hatch-Waxman regulatory regime to work as intended, Teva developed a "Generic Defense Strategy" that comprised shifting the market to a different dosage—the 40mg dose.[9] Because a 20mg GA is not automatically substitutable for 40mg Copaxone, shifting the market to 40mg would prevent the generic 20mg product from taking shares away from branded Copaxone in the manner ordinarily expected in a competitive market. To implement this strategy, Teva engaged in several tactics designed to switch prescribers, patients, and payers from the 20mg to the 40mg product, beyond what any incremental benefit of the new dosage would have been able to achieve in the same timeframe.

[9] *See* House Teva Report, *supra* note 1, at 24.

113. The role of this "Generic Defense Strategy" in Teva's anticompetitive scheme cannot be overstated. In its Q1 2014 quarterly filing, Teva explained that its "business strategy for Copaxone® relies heavily on the successful introduction of Copaxone® 40 mg/mL and the migration of a substantial percentage of current daily Copaxone® patients to this new version," and that "failure to continue to achieve [Teva's] objectives for the new version would likely have a material adverse effect on [Teva's] financial results and cash flow." As explained below, Teva's tactic succeeded in significantly blunting the impact of generic competition.

1. Teva Timed the Launch of the 40mg Product to Preempt Generic Competition to the 20mg Product, in Conjunction with Delaying Generic Launch Through Abuse of Regulatory Processes and Court Filings

114. The first component of Teva's strategy was timing. Long before the first generic had filed its ANDA for the 20mg strength, Teva had been planning the switch to the 40mg product to preempt generic competition. In particular, from at least 2003, Teva had been sponsoring clinical trials to examine the efficacy of 40mg as a daily dosage. However, when a Phase III trial showed in July 2008 that the 40mg dosage as a daily regimen is not more effective than the daily 20mg regimen, Teva had no choice but to pivot to exploring the 40mg dose as a less frequent and more convenient regimen. For context, Teva had previously rejected this less-frequent dosing regimen strategy as less profitable.[10]

115. However, when the more profitable potential strategy of 40mg once-a-day failed, and upon receiving the Paragraph IV certification from Sandoz for the 20mg product, Teva was forced to propose this pathway of 40mg in a less frequent regimen as a new "Life Cycle Initiative[]" to its Board of Directors in July 2008.[11] As its name suggests, the initiative is meant to extend the "life cycle" during which the franchise remains valuable to Teva, *i.e.*, insulated from generic competition. Indeed, even when Teva had to choose a less profitable course than the potential daily 40mg regimen in order to preempt generic competition, it still endeavored to

[10] *Id.*
[11] *Id.*

maximize the price that patients and payers would have to pay for Copaxone 40mg. In particular, Teva decided against doing research on the efficacy of a once-a-week dosing regimen (which would have been more convenient for patients than three times a week) because Teva's then CEO was concerned that this regimen would cause patients to take two injections of the more affordable generic GA 20mg than the once-per-week branded Copaxone 40mg.[12] Rather, the real purpose of introducing the 40mg product and shifting the market to this product was to create a "Barrier to Generic entrance." Teva sought to conceal this real purpose by suggesting in an internal document to change the phrase to "extension of Life Cycle and new IP" because it did not "want to be[] seen as 'creating' barriers to generics as this is Teva's core business."[13]

116. In conjunction with exploring the less frequent dosage pathway, Teva also started considering whether to "patent the frequency" in August 2008, which would delay generic competition to the 40mg dosage. Ultimately, the patents Teva obtained for the 40mg product included such claims regarding dosing frequency, which were subsequently invalidated by the PTAB, district court, and Court of Appeals for the Federal Circuit. In December 2008, faced with a pending ANDA for the 20mg product, Teva decided to pursue research supporting the three-times-a-week regimen for the 40mg dose.

117. The pressure continued to mount in the following years. For example, a June 2009 Teva presentation emphasized the "need to develop a low frequency formulation of GA to [e]nsure the competitiveness of Copaxone in the future . . . . The new formulation must be approved no later than 2014." Teva considered conducting a study to support the 2-3 times/week regimen, but because of the time pressure proposed "not [to] consult with regulatory authorities before study initiation – they will most probably not accept this design."[14] Teva started applying for the 40mg patents in August 2009 and, after the clinical study demonstrated that the three times per week dosage was safe and effective, filed its sNDA for the 40mg dose in 2013.

---

[12] *Id.* at 28.
[13] *Id.* at 29.
[14] House Teva Report Document Packet, *supra* note 1, Document 48.

118. Upon receiving FDA approval for the 40mg product on January 28, 2014, just four months before expiration of the 20mg patents, Teva immediately launched it.

2. Teva Shifted the Market to 40mg Through Economically Irrational Pricing, and Anticompetitive Tying and Agreements

119. Having launched the 40mg product just before the 20mg patents expired, the other component to Teva's strategy was to quickly switch as much of the market from 20mg to 40mg as it could, beyond those that would switch to the 40mg on their own, while continuing to delay generic competition to the 20mg through its abuse of the regulatory processes and court filings long enough for the market shift to be effectuated. Teva accomplished this market shift through: 1) economically irrational pricing, 2) tying the rebates on the 20mg product to the purchase of the 40mg product, 3) anticompetitive agreements with other industry stakeholders, and 4) a marketing campaign targeted at doctors and patients.

120. First, Teva set the launch price for Copaxone 40mg lower than the weekly price of Copaxone 20mg. If, as Teva claims, the 40mg product is better than the 20mg product in some respect, then it would be economically irrational for a profit-seeking firm like Teva to charge less for the allegedly better product. Teva's pricing committee's memorandum approving this pricing decision confirmed that the purpose of the pricing irregularity was to propel the "rapid transition of COPAXONE 20mg to 40mg prior to expected generics in mid-2014."[15]

121. Shortly thereafter, Teva went even further by increasing the price of Copaxone 20mg by 9.8% in August 2014 to further drive patients and prescribers to the 40mg product. This price increase for the 20mg was later than some Teva executives would have liked, given their concerns about preempting generic competition to the 20mg product: "Just for clarity … an important part of our generic defense strategy is creating price separation between 20mg and 40mg. We can do that via increased discounts on 40mg or raising the price on 20mg. I prefer the latter. Delaying a pricing action to mid-August or later, impedes our ability to gain access for

[15] House Teva Report, *supra* note 1, at 30.

40mg with resistant payers, makes a generic more appealing to payers, and could dampen further conversion strategies."[16]

From: Katie Hiett
Sent: Tuesday, July 1, 2014 7:56 PM
To: Brendan O'Grady
Subject: Re: APPROVAL REQUIRED: COPAXONE 20MG JULY 2nd, 2014 PROPOSED PRICE INCREASE

Maybe we still have time to convince them to sit on the CP until FDA accepts or separate it from the price increase.

Sent from my iPhone

On Jul 1, 2014, at 6:10 PM, "Brendan O'Grady" **Highly Confidential** wrote:

> Just for clarity...an important part of our generic defense strategy is creating price separation between 20mg and 40mg. We can do that via increased discounts on 40mg or raising the price on 20mg. I prefer the latter. Delaying a pricing action to mid-August, or later, impedes our ability to gain access for 40mg with resistant payers, makes a generic more appealing to payers, and could dampen further conversion strategies.

122. To further widen the pricing gap between the 20mg and 40mg products, Teva also considered a plan to "Discontinue 20mg Financial Programs," which it had been using to keep patients on the brand product despite Copaxone's supracompetitive pricing. Clearly, whatever justifications Teva had for paying kickbacks to Medicare Part D patients through purported "donations" to third-party foundations, those justifications were trumped by Teva's need to quickly shift the market to the 40mg and insulate Copaxone from the impending generic competition.

123. Second, Teva removed the choice from purchasers by tying the rebates for the 20mg to the distribution of the 40mg product. While companies typically deploy a tying strategy to leverage the monopoly power of one product onto another to extract more revenue, in this instance Teva leveraged its monopoly power over 20mg to induce adoption of the 40mg product. Specifically, in Teva's contracts with PBMs, it conditioned contractual rebates for Copaxone 20mg on the addition of Copaxone 40mg to the PBMs' formularies. The rebates ordinarily would be passed through from the PBMs to payers in whole or in part, and by tying the rebates for the 20mg product to the 40mg product in the manner described here, Teva threatened to withhold discounts to PBMs and payers if they did not agree to provide insurance coverage for the 40mg.

[16] *Id.*

This eliminates a choice that PBMs and payers normally can and often do make, *i.e.*, to encourage patients to use less expensive drugs—here generic GA 20mg when it would eventually launch—by refusing to cover the more expensive drugs—here branded Copaxone 40mg.

124. Teva's internal documents demonstrate the coercive effect of this tying tactic. Specifically, Teva's internal emails show that one PBM forfeited its 2015 rebates on Copaxone 20mg because it refused to add Copaxone 40mg to its formulary. However, the PBM reversed its position the following year, on information and belief, due to the effect of the foregone rebates, and acquiesced in adding Copaxone 40mg to its formulary.[17] Thus, Teva's tying succeeded in preventing the PBM and its insurance carrier from facilitating the switch to generic GA 20mg by coercing them into covering the Copaxone 40mg (which was more expensive than generic GA) just as generic GA 20mg launched.

125. Third, in addition to the tying agreement, Teva also entered into anticompetitive agreements with PBMs to divert prescribers from the 20mg to the 40mg product. For example, after generic GA 20mg had launched in 2015, Teva contracted with the insurer Humana to implement a "Copaxone conversion initiative."[18] Pursuant to this agreement, "Humana is committed to converting current Copaxone 20mg patients over to Copaxone 40mg with their physician members." In particular, Humana contacted "the prescribers via fax and phone to make them aware of which patients are still on Copaxone 20mg and encourage them to switch these patients to Copaxone 40mg." In exchange, Teva provided payments to Humana to incentivize it to continue the implementation of this switching strategy.

126. Finally, to aid in the initial switching of the market as well as ensure that Copaxone continued to be insulated from competition before a generic GA 40mg came to market, Teva also executed a marketing campaign to encourage patients and physicians to switch to the 40mg product that continued even after generic GA 20mg had launched. For example,

[17] *Id.* at 31.
[18] *Id.* at 32.

Teva's 2017 "Brand Plan"[19] set out the following "Behavioral Objectives" for its salesforce to convert physicians to:

- "Encourage physicians to initiate and upgrade any remaining patients to TIW [three times weekly] Copaxone 40mg";
- "Encourage physicians to switch patients to TIW Copaxone 40mg if payers force to generic GA for daily dose";
- "Prescribe Copaxone DAW [Dispense as Written] for new and existing patients"; and
- "Encourage their patients to accept only branded Copaxone."

127. To convert the physicians, Teva's sales efforts included direct visits with the physicians, organization and sponsorship of industry events, print advertising and articles in industry publications, and the publication and promotion of scientific literature. Additionally, to further influence patient decisions, Teva also used its patient portal, Shared Solutions, to encourage them to switch from the 20mg to the 40mg product. Teva supplemented its strategies for shifting the market from 20mg to 40mg by consistently denigrating generic GA,[20] a strategy that Teva repeated and doubled down on with a misrepresentation campaign in 2017 to similarly impede generic uptake of generic GA 40mg, as described below.

3. Teva's Market Shifting Strategy

128. Teva's "Generic Defense Strategy" succeeded in rapidly and significantly shifting the market from the 20mg product to the 40mg product just in time to blunt the effect of generic competition. Even the FDA, which does not normally address competition issues, has noted that Teva's market-shifting tactics extended its franchise on Copaxone. In a court filing

[19] *Id.*

[20] *See, e.g.*, Ben Comer, *Copaxone: Built to Last*, PharmExec.com (May 1, 2014) (observing that "Teva has expressed doubt, in print and at just about every other opportunity, over the comparative effectiveness and safety of generic Copaxone" in response to a Teva Vice President and general manager's statement that generic GA is "unproven"), https://www.pharmexec.com/view/2014-brand-year.

defending against a lawsuit by Teva to prevent the FDA from approving GA ANDAs, the FDA stated that Teva "vigorously convert[ed]" 20mg patients "to the new 40 mg/mL dosage form, for which Teva has listed patents that do not expire until 2030." The FDA further noted that "[a]s of April 18, 2014, the company had succeeded in converting 31% of Copaxone prescriptions in the United States to the new 40 mg/mL dosage form."

129. Similarly, Teva's then-CEO explained in December 2015 that it had converted 76.9% of Copaxone patients to 40mg and had limited "Glatopa 20mg Market Share" to 19.3%. More directly, in June 2016, Teva's internal documents confirmed that "[t]he strategy of switching patients to 40mg version of the medicine is continuing to be successful and reduce the impact of generic competition."[21] Thereafter, in October 2017, a consultant that Teva hired to advise on combating generic competition to the 40mg again confirmed the effectiveness of Teva's market-shifting strategy: "Prior to Glatopa's launch, Teva released and promoted a long-acting Copaxone 40MG, effectively pushing existing and new patients to the branded 40MG and minimizing generic substitution."[22] Thus, because of Teva's anticompetitive tactics, a significant number of patients and payers were forced to continue paying for branded Copaxone instead of the more affordable generic GA 20mg. These include those patients and payers who would have switched to the generic but for Teva's coercion through, *inter alia*, tying the rebates for Copaxone 20mg to coverage of the 40mg product.

130. After switching the market away from the 20mg product, which faced generic competition, Teva was able to continue increasing prices for the Copaxone franchise by increasing prices for the 40mg product, which faced no generic competition. Specifically, Teva's internal data show that every year since 2014, the average negotiated payer discount to commercial and Medicare Part D plans for Copaxone 40 mg was lower than Copaxone 20 mg, with the difference in the commercial channel exceeding 10% in some years.[23] Researchers at

[21] House Teva Report, *supra* note 1, at 33-34.
[22] *Id.* at 34.
[23] *Id.*

Harvard University estimated that Teva's market shifting strategy created a 2.5-year delay in full generic competition and cost the U.S. health care system between $4.3 and $6.5 billion in overcharges.

B. Teva's DAW Campaign Through False and Misleading Promotional Statements

131. Teva has spent millions of dollars to promote Copaxone, including through a team of sales representatives ("sales reps"). These sales reps regularly visit medical professionals who treat MS patients and their staffs across the nation to persuade medical professionals to prescribe Copaxone. Teva also promotes Copaxone through its Shared Solutions patient support hub. Shared Solutions provides copay support that can reduce copays to $0 for appropriate patients, training and nurse support, and other educational resources. Teva nurses not only visit with MS patients, but they also visit doctors' offices and talk to medical professionals and their staffs about Copaxone.

132. In the months leading up to the launch of Mylan's generic GA in October 2017 and for at least several months thereafter, Teva, through at least its sales representatives and Shared Solutions personnel, began a campaign to deliberately mislead medical professionals and MS patients about the effectiveness of Mylan's GA product and the availability of Mylan MS Advocate services, in order to influence prescribing behavior. Specifically, notwithstanding the FDA's determination that Mylan's GA is therapeutically equivalent to Copaxone and the lack of any evidence to the contrary, Teva sales reps began telling medical professionals and their staffs during office visits that generic GA is only 80% or only 85% as effective as Copaxone (the "Less Effective Statements"), that Mylan does not provide copayment support for its generic GA (the "No Copay Support Statements"), and that Mylan does not provide training and nursing support for its generic GA (the "No Nursing Support Statements"). Teva's Shared Solutions personnel also made the No Copay Support and No Nursing Support Statements directly to MS patients.

133. Through these false and misleading statements, Teva persuaded doctors to "[p]rescribe Copaxone DAW for new and existing patients" and patients to request such prescriptions. The effect of this strategy is to circumvent the automatic substitution laws that would require or permit pharmacists to replace the more expensive branded Copaxone with more affordable generic GA. That is, if the doctor writes a DAW prescription, the pharmacist would be prevented from substituting branded Copaxone with the generic drug, even though generic GA is an A-rated bioequivalent drug to branded Copaxone. Thus, this tactic undermines a key legislative mechanism by which generic GA should compete with Copaxone. Indeed, Teva's strategy documents confirmed this DAW campaign through misrepresentations as one of the core components in its scheme to limit generic competition. For example, a January 2017 presentation titled "At-Risk Gx Readiness" explained: "HCP [health care professional] loyalty and DAW strategy will help retain many of these branded units [in insurance plans that may decide to add generic to their formulary]."[24]

134. Further, when Mylan's generic GA launched in October 2017, Teva intensified this DAW campaign through misrepresentations as one of its "Key Activities to Defend Against Generic Erosion." Teva's presentation to its Board of Directors emphasized "[o]utbound efforts to 40mg patients through Shared Solutions," including sending "[e]mails to all patients with DAW messaging."[25] Teva's executives also touted their "[a]bility to produce current 40mg patient lists for HCP [health care professional] offices" to "proactively" write DAW prescriptions.[26] The campaign continued thereafter, with Teva "reinforce[ing] DAW on every call" and using "Marketing driven patient programs and telecons to supplement patient education/support."[27]

[24] House Teva Report Document Packet, *supra* note 1, Document 53.
[25] *Id.*, Document 44.
[26] *Id.*
[27] House Teva Report, *supra* note 1, at 23-24.

1. The "Less Effective" Statements

135. As Mylan's sales representatives started their own visits to medical professionals who treat MS, they were surprised to find that many would not even speak to Mylan. They were told over and over by medical practices throughout the country that the prescribers were not interested in Mylan's GA because it "is only 80% as effective as Copaxone" or it "is only 85% as effective as Copaxone."

136. Mylan representatives consistently encountered this response from numerous medical practices throughout the country, including from health care providers in Ohio, Pennsylvania, Texas, and California.

137. The Less Effective Statements are literally false. The FDA determined that Mylan's generic GA is an "A" rated therapeutically equivalent substitute for Copaxone and therefore just as effective. There is no study showing that Mylan's GA is only 80% or 85% as effective as Copaxone.

138. The Less Effective Statements have been disseminated widely among GA prescribers, and a significant portion of the prescribers who have been exposed to the statements attribute them to Teva and sales reps.

139. Teva knew that the Less Effective Statements were false. There are no comparative efficacy trials of Copaxone against Mylan's GA product.

140. Teva's representations that Mylan's GA product was less effective than Copaxone were inconsistent with the FDA's determination that Mylan's GA is an "A" rated therapeutic equivalent of Copaxone.

141. Furthermore, Teva knew that invocation of an 80-85% effective standard was misleading. An 80% to 125% standard refers to a standard of blood absorption rate and concentration that is used to evaluate the bioequivalency of generic drugs in the context of human trials. However, Teva knows that the FDA did not require human trials for Mylan's generic GA because the drug is an injectable and therefore bioequivalency to Copaxone was

"self-evident." The standard Teva is invoking through its Less Effective Statements does not apply to Mylan's generic GA at all.

2. The No Copay Support Statements

142. Teva's sales reps and Shared Solutions personnel have falsely told medical professionals and MS patients that Mylan does not offer copay support in connection with its generic GA product.

143. Numerous doctors, nurses, and medical office staff across the country have reported to Mylan representatives their understanding that Mylan's GA does not come with copayment support. This includes medical professionals in Cleveland, Ohio; Detroit, Michigan; and Pittsburgh, Pennsylvania.

144. A nurse at Allegheny General Hospital in Pittsburgh, Pennsylvania attributed a No Copay Support Statement to Teva's Shared Solutions. She reported that her patients were calling her crying because they feared being switched to generic GA and having to pay the copay out of pocket.

145. The No Copay Support Statements have been disseminated widely among GA prescribers, and a significant portion of the prescribers who have been exposed to the statements attribute them to Teva sales reps.

146. Teva knew or acted in reckless disregard for the truth as to whether Mylan also offers copay support to patients taking its generic GA product. In its October 3, 2017 press release announcing that the FDA had approved its generic GA product, Mylan explained that MS Advocate would offer "copay assistance for eligible patients." However, Mylan representatives' communications with health care providers indicated that Teva continued to make the No Copay Support Statements after this date.

3. The No Nursing Support Statements

147. Teva's sales reps and Shared Solutions personnel also have falsely told medical professionals and MS patients that Mylan does not provide patient training and nursing support for its generic GA product.

148. Numerous doctors, nurses and staff across the country have reported to Mylan representatives their belief that Mylan's GA product does not come with patient support, such as training and nursing assistance. This includes medical professionals in the Long Beach, California and San Antonio, Texas areas.

149. A nurse in the Long Beach, California area attributed a No Nursing Support Statement to a Teva representative.

150. The No Nursing Support Statements have been disseminated widely among GA prescribers, and a significant portion of the prescribers who have been exposed to the statements attribute them to Teva sales reps.

151. Teva knew or acted in reckless disregard for the truth as to whether Mylan also offers training and nursing support to patients taking its generic GA product. In its October 3, 2017 press release announcing that the FDA had approved its generic GA product, Mylan explained that MS Advocate would offer "in-home injection training," "a 24/7 patient support center," and "ongoing support from an MS-experienced nurse." However, Mylan representatives' communications with health care providers indicated that Teva continued to make the No Nursing Support Statements after this date.

4. Additional False and Misleading Statements

152. In addition to the Less Effective, No Copay Support and No Nursing Support statements, Teva through its sales representatives and Shared Solutions personnel has disseminated numerous additional false and misleading statements to medical professionals and MS patients.

153. Numerous medical professionals have expressed a reluctance to allow their MS patients to be switched to Mylan's GA product because of their belief that Mylan's GA product is a more complex drug called a "biologic" or "biosimilar."

154. In fact, Mylan's GA product is not a biologic or biosimilar.

155. For example, one doctor in the San Antonio, Texas area cancelled a Mylan lunch at her clinic, explaining that drugs "like Copaxone" were "being replaced by biosimilar that are supposedly similar," but "[u]nlike simple molecules that can be copied and reproduced, biosimilar and follow-on complex drugs" are too complicated. The doctor concluded that she "support[s] Teva."

156. Similarly, on May 16, 2018, one nurse in Central California said that a Teva representative had told her that the Mylan generic GA product was not the same medication as Copaxone and that her patients would suffer from switching. When told by Mylan that the medications were the same, she became angry and warned that she was going to report the Mylan employee to her Teva representative.

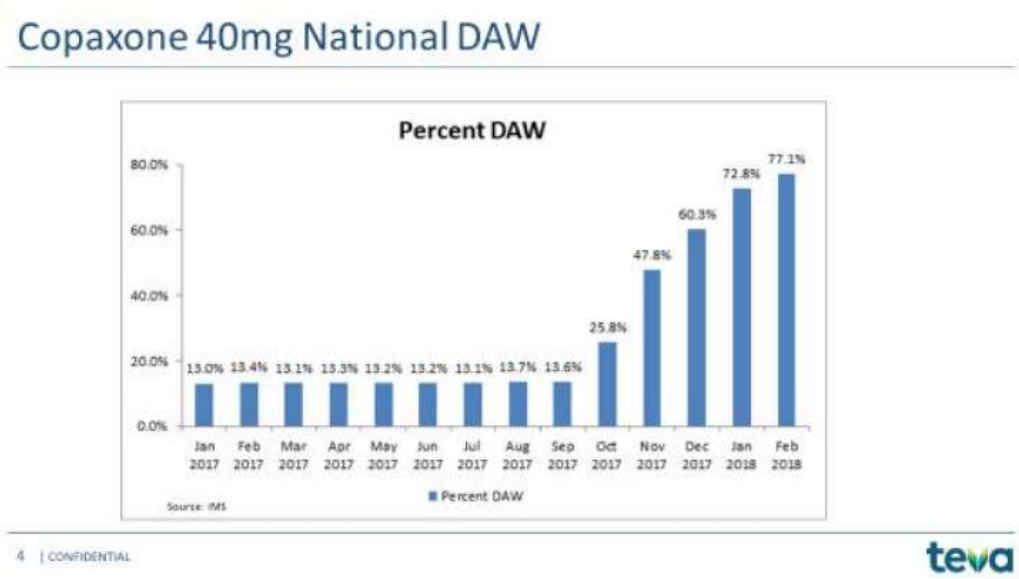
157. A doctor in Southern California argued with a Mylan representative that Mylan's generic GA product is materially different from Copaxone.

158. Mylan's sales representatives frequently have encountered such statements from medical professionals throughout the United States, which reflects a coordinated campaign by Teva to spread misinformation about Mylan's GA product through its sales representatives and Shared Solutions.

159. Upon information and belief, the medical professionals who believe that a generic GA product is a biologic or biosimilar, or otherwise materially different from Copaxone, were told so by Teva. Teva knew that these statements were false or acted in reckless disregard of the truth.

5. Teva's Misrepresentation Campaign Succeeded in Preventing Generic Uptake

160. Through its false and misleading promotional statements and well as other marketing tactics, Teva successfully persuaded a large number of doctors to write DAW prescriptions for Copaxone and patients to request them. As a result, whereas the DAW prescription rate for Copaxone was consistently approximately 13.5% leading up to Mylan's launch in October 2017, it rose to at least 77% by February 2018.



161. Other internal Teva documents similarly show that the misrepresentation campaign achieved its purpose. For example, an August 2018 email from Teva's Executive Vice President for North America read: "Keep up pressure on Copaxone and maximize office calls up to the launch of [another Teva product]. The DAW campaign combined with the legacy and house brand access strategy has paid great dividends. I want to exceed $1.5b for the year on Copaxone. We did $900m in H1 so we only need to do $500m+ in H2 to accomplish this goal."[28] Teva in fact exceeded this goal, earning $1.6 billion in net revenue in 2018, despite the presence

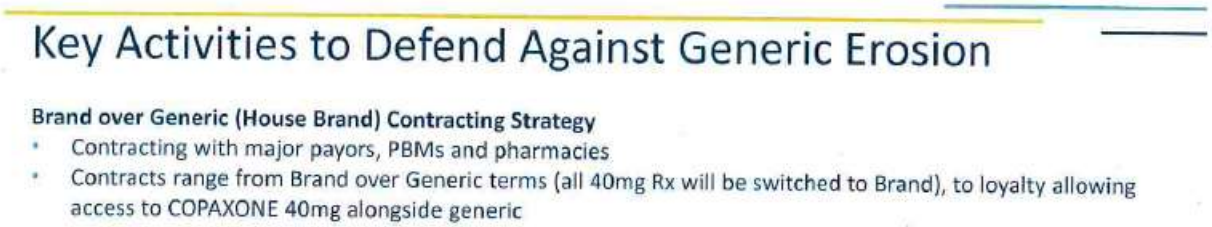
[28] *Id.* at 40.

of generic competition and the fact that Mylan cut its list price for generic GA 40mg by 60% in July 2018.

162. Mylan endeavored to correct the misrepresentations Teva had spread through its sales representatives. However, for a long time, its efforts had very limited impact because several health care providers would not even talk to Mylan's sales representations due to Teva's misrepresentations, while many others argued with Mylan's representatives using false statements provided by Teva.

C. Teva's Agreements with PBMs and PBM-Owned Specialty Pharmacies to Exclude Generic GA from Formularies and Dispensing

163. Whereas much of Teva's earlier-in-time activity had been directed at preventing the introduction of a generic competitor, like the market-shifting strategy and abuse of regulatory processes and court filings, the goal of the PBM/Specialty Pharmacy plan was to prevent a lower-priced generic GA product from competing effectively and to allow Teva to continue reaping supracompetitive profits. Teva's October 2017 Generic Copaxone 40mg Update identified as its first "key activity to defend against generic erosion" the need for Teva to engage in "Brand over Generic (House Brand) Contracting Strategy."[29]



164. Congress described Teva's anticompetitive strategy, noting, "When Mylan received FDA approval on October 3, 2017, to bring its generic version of Copaxone to market, Teva immediately began executing the House Brand Strategy."[30] The strategy included forcing PBMs to exclude generic GA from formularies by refusing to pay any rebates at all unless

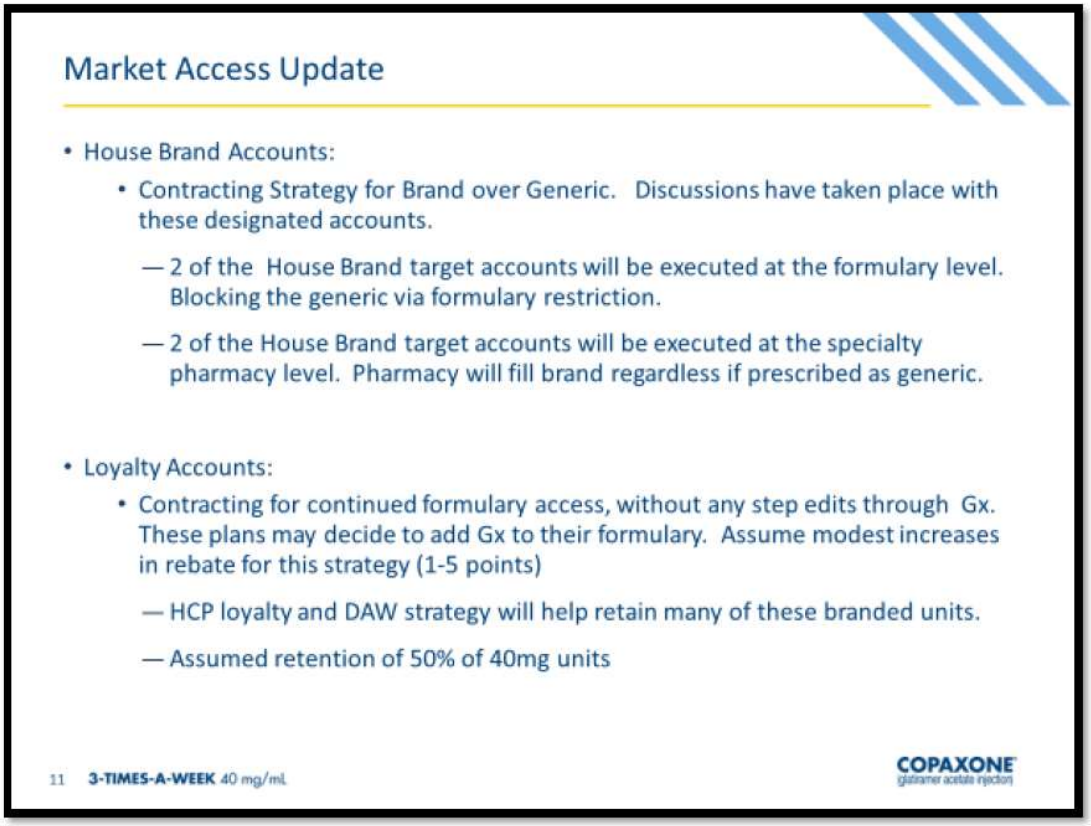
[29] House Teva Report Document Packet, *supra* note 1, Document 44.
[30] House Teva Report, *supra* note 1, at 31.

generic GA is excluded, and paying PBM-owned specialty pharmacies to switch generic prescriptions to Teva's branded Copaxone regardless of the prescription and even when the generic GA is covered on formulary.

165. Through its House Brand strategy, Teva entered into arrangements with key PBMs whereby Teva conditioned the payment of rebates and, on information and belief, other concealed payments and/or inducements to PBMs or corporate relatives of the PBMs, on the complete exclusion of generic GA from formularies, such that generic GA would not be covered by insurance. Teva described this as "executed at the formulary level" and resulting in "blocking the generic via formulary restriction." Teva's strategy was not the typical rebating that defines the brand-PBM formulary relationship. For starters, Teva's rebates spanned at least two products, was an all-or-nothing offer to PBMs that the House Teva Report described as "Teva exert[ing] pressure on PBMs," and excluded a lower-priced generic product.

166. More impactful, however, was Teva's coupling of formulary-blocking with bait-and-switch agreements that incentivized PBM-owned specialty pharmacies to replace generic GA with Copaxone, regardless of scripts or formularies. As part of its House Brand strategy, Teva paid the PBM-owned specialty pharmacies to switch generic prescriptions with branded Copaxone at the pharmacy level, further blocking Mylan and other generic competitors from accessing the market. Teva described this as "executed at the specialty pharmacy level" where "[the pharmacy] will fill brand regardless if prescribed as generic." Teva has entered into these arrangements with at least the specialty pharmacy owned by one of the largest PBMs. Documents obtained from the Congressional investigation suggest that Teva has similar arrangements with other PBMs and specialty pharmacies. These arrangements subvert automatic substitution laws, a key mechanism designed to facilitate generic competition to lower costs to consumers and payers.[31]

[31] Teva supplements its House Brand Strategy with increased rebates payments to payers who want to include a generic on the formulary.



[32]

167. In a series of emails in January 2018, Teva's Executive Vice President for North America explained that Teva's House Brand agreement with a specialty pharmacy successfully prevented generic competition because the insurer's decision to move branded Copaxone to non-preferred tier had "almost zero impact on actual prescriptions" and "[b]ecause [PBM] is getting an additional rebate to fill all 'glatiramer' or Copaxone scripts with Copaxone … if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all….[the specialty pharmacy] only ships brand Copaxone no matter how it is written or what the formulary states. That is why [putting Copaxone on non-preferred tier] has little impact." There can be no doubt as to the efficacy of such a ploy – Teva's own documents confirm that "95% of [insurer's pharmaceutical

[32] House Teva Report Document Packet, *supra* note 1, Document 53.

purchasing] is mail order through [specialty pharmacy],” so Teva’s House Brand strategy affected the vast majority of this insurer’s beneficiaries.[33]

Because they are looking at the future...this has almost zero impact on actual prescriptions – I will explain later. Also, the NP status means little as we buy the patients copay down to zero anyway. Unless they NDC block Copaxone 40mg, we are fine. That is why they did not inform the reps because the actual impact is very low and it would just confuse them.

Best regards,

<image001.png> Brendan P. O'Grady EVP and Head of North America **Highly Confidential**

<image002.png>

From: [redacted]
Sent: Wednesday, January 31, 2018 1:02 PM
To: Brendan O'Grady
Subject: FW: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Hi,

I thought I would take you down five million levels and let your brain totally veg out on things so below your pay grade.

I realize we have the Specialty Pharmacy House Brand Strategy that will lessen the blow on this Insurer decision, but – do why would a plan of this size make this type of move if they were being offered a rebate that made a brand drug more economical than a generi? (at least I am assuming that is the case, but haven’t spoken to [redacted] about it yet, as it is not official that this is my account.)
Wish you weren’t so important and busy with higher level decisions and control – I need you as my mentor! Ahahahha!

[33] *Id.*, Document 54.

To: Brendan O'Grady
Subject: Re: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Ok- thanks. I thought they only received that for non- mail order and since 95% of Insurer is mail order through Specialty Pharmacy it doesn't sound so great, so I obviously need to understand it better

Sent from my iPhone

On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

> Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone...if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all...
>
> Best regards,

On Jan 31, 2018, at 4:02 PM, Brendan O'Grady Highly Confidential wrote:

> No as last I understood, Specialty Pharmacy only ships brand Copaxone no matter how it is written or what the formulary states. That is why this has little impact. Then again, my knowledge may be dated.

168. Teva's arrangement makes no economic sense absent an agreement by and among Teva and the PBMs/specialty pharmacies to exclude generic GA and maintain Teva's monopoly.

169. Teva's executives purposefully did not disclose the House Brand strategy to its salespeople because of the "confidential nature" of this strategy and because the actual sales impact of the insurer's placement of Copaxone on a non-preferred tier was "very low" due to the effectiveness of Teva's strategy. Instead, Teva's executives encouraged its sales team to "use DAW as their reactive response"—*i.e.*, create more lies regarding the true motive and mechanism generating Teva's Copaxone sales.

D. Teva's Anticompetitive Use of Illegal Kickbacks

170. For more than a decade, Teva has been "investing" in its third-party foundations to pay off patient copays for Copaxone through illegal kickbacks, thus keeping them on Copaxone instead of switching to more affordable alternatives. When generic GA came to

market, Teva continued to use these payments, in conjunction with other anticompetitive tactics such as its misrepresentation campaign, to keep patients on Copaxone in circumstances where they would otherwise switch to the more affordable generic, either on their own initiative or through insurance tier management by payers. As a result, Teva's use of illegal kickbacks contributed to the reduced generic uptake that is otherwise ordinarily expected in a competitive market.

171. Because Teva's illegal kickbacks to third-party foundations pay off Medicare patients' copay obligations, they remove the patients' incentive to seek the more affordable generic GA, the copay for which would have been lower than the copay for branded Copaxone but for Teva's illegal kickbacks. Consequently, Teva retained these patients on Copaxone when they otherwise would have switched to generic GA. On the other hand, insurers and the federal government were forced to continue to pay Teva the higher, unsubsidized price of branded Copaxone, rather than the lower price of generic GA.

172. Teva's internal documents show that Teva's "donations" to third-party foundations were in fact "investments" to drive Copaxone sales, rather than *bona fide* charitable assistance. For example, Teva's 2008 Copaxone Work Plan estimated that the company would spend approximately $97 million on "Medicare Financial Assistance" between 2008 and 2011 and that this expenditure would result in the sale of an additional 155,113 units of Copaxone that were "incremental" or "not lost."[34] The work plan also described the expected reductions in sales if Teva decreased its Medicare grant investments. Similarly, an August 2017 email from Teva's Vice President of Finance for North America Specialty Medicines expressed his discomfort with "including the sales impact of the reduced donations."[35] He also confirmed that "reducing the level of donations could mean that a significant number of patients will not be able to remain on Copaxone due to financial constraints," which would include patients who would otherwise have switched to generic GA.

[34] *Id.* at 15.
[35] *Id.* at 20.

173. Teva's illegal kickbacks were the subject of a DOJ lawsuit filed on August 18, 2020. DOJ alleged: "During the period from late 2006 through at least 2015, Teva knowingly and willfully violated the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), by paying over $300 million to two third-party foundations, Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"), to cover the Medicare copay obligations of Copaxone patients." According to evidence obtained by the DOJ, Teva made payments only to these two foundations because "it had assurance that its money would go to patients taking its drug, Copaxone," rather than to patients taking other drugs. Indeed, Teva had previously made payments to another copay foundation, but was "burned" when the payments were used to cover the copays of patients on other drugs. Teva's decision to stop making "donations" to that foundation confirms that the sole purpose of Teva's payments to third-party foundations was to keep patients on Copaxone. Data obtained by Congress in its recent investigation also show that Teva's kickbacks to these foundations continued for at least three years beyond the scope of the DOJ complaint.

174. Teva's subsidization of patient copay through its illegal kickbacks to third-party foundations compounded the anticompetitive effect of its various other conduct to inhibit generic competition, and in turn was made more effective at stifling competition because of the other conduct. Generic manufacturers, after finally obtaining FDA approval and launching despite Teva's delaying tactics, and getting on the formularies that were not already blocked off by Teva's anticompetitive agreements with PBMs, were unable to benefit payers because Teva drove a substantial number of patients to its branded product by paying off their copays through illegal kickbacks.

175. A January 2018 internal Teva email explains this effect well.[36] The email discusses an insurer's decision to move Copaxone 40mg to non-preferred status for both Commercial and Medicare Part D plans, covering approximately 15 million and 1 million lives respectively. Pursuant to this change, requests for branded Copaxone 20mg and 40mg must meet

[36] House Teva Report Document Packet, *supra* note 1, Document 54.

several criteria to be covered, one of which was that the "[i]ndividual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following . . . Glatiramer 20mg/ml, glatiramer 40mg/ml, or Glatopa 20mg/ml." Teva's Executive Vice President for North America explained why this insurer's attempt to facilitate conversion to less expensive generic GA failed: "Also, the NP [non-preferred] status means little as we buy the patients [sic] copay down to zero anyway. Unless they NDC block Copaxone 40mg, we are fine . . . the actual impact is very low . . ."

E. Teva's Strategy of Abuse of Regulatory Processes and Court Filings Including Teva's Baseless Lawsuit Against the FDA to Reclassify Copaxone as a Biologic

176. Finally, just as generic GA products started to gain some limited market shares, albeit at a rate dramatically lower and slower than expected in competitive markets, Teva returned to its tried-and-true strategy of abuse of regulatory processes and court filings, which had delayed the launch of generic GA. This time, Teva's baseless regulatory and court filings were designed to completely eliminate generic competition to Copaxone. That is, Teva asked the FDA to reclassify Copaxone as a biological product under the PHSA, which, if granted, would have immediately eliminated automatic substitution with generic GA products unless and until the FDA took certain additional steps. When the FDA denied Teva's reclassification request, Teva repeated its playbook and filed a baseless lawsuit against the FDA on March 24, 2020, making arguments that directly contradicted its own previous positions taken before the agency.

177. Before the enactment of the BPCIA in 2010, the PHSA defined "biological product" as, among other things, "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product." 42 U.S.C. § 262(i)(1) (2006). In addition to creating an abbreviated approval pathway for biosimilar and interchangeable biological products, BPCIA also amended the definition of "biological product" in the PHSA to include a "protein (except any chemically synthesized polypeptide)" or analogous product. *See* 42 U.S.C. § 262(i)(1) (2010). The BPCIA provided for the transition of

drug products determined by the FDA to fall within a revised definition of "protein" which were previously approved through NDAs, to be reclassified as biologics deemed to be a BLA under the PHSA. The reclassification became effective on March 23, 2020.

178. In February 2012, the FDA issued a draft guidance document explaining the FDA's interpretation of the terms "protein" and "chemically synthesized polypeptide." Teva submitted several comments regarding this draft guidance, but they did not address the FDA's interpretation of these terms. Rather, Teva proposed its own interpretation to serve its arguments that Copaxone is a protein in a separate Citizen Petition requesting the FDA not to approve GA ANDAs. The FDA's denial of that Citizen Petition rejected Teva's interpretation, and the FDA further explained this point in its denial of a subsequent Teva Citizen Petition in 2015.

179. In December 2018, the FDA proposed a rule codifying its interpretation of "protein" and "chemically synthesized polypeptide." It also published a preliminary list of approved NDAs that would be deemed to be BLAs on March 23, 2020. Copaxone was not on the list. The FDA updated the preliminary list periodically through January 2020, and at no point was Copaxone listed.

180. In December 2019, the Further Consolidated Appropriations Act of 2020 struck the phrase "(except any chemically synthesized polypeptide)" from PHSA's definition of "biological product." Pub. L. 166-94 § 605. In February 2020, the FDA finalized the portion of the proposed rule regarding its interpretation of "protein," but not the portion regarding "chemically synthesized polypeptide" because it was struck from the statute.

181. On February 19, 2020, Teva submitted comments to the FDA requesting that FDA include Copaxone in the list of approved NDAs to be transitioned to BLAs. Teva argued that Copaxone was a protein or an "analogous product" to a protein, and therefore should be reclassified as a biologic.

182. On March 20, 2020, the FDA determined that Copaxone is not a biological product and memorialized this decision in an internal memorandum. Accordingly, the FDA

denied Teva's request by refusing to include Copaxone on the finalized list of reclassified products.

183. On March 24, 2020, the day after the transition became effective, Teva sued the FDA in district court. Teva's complaint alluded to its anticompetitive purpose: "Had FDA transitioned the COPAXONE NDA to a deemed license, an applicant seeking to rely on COPAXONE's approval to make an equivalent product would have to undergo the biosimilar application process." Teva argued that the reclassification would allow Teva to sue a new, unnamed prospective ANDA filer, alleging infringement of certain process patents, which is not possible under the Hatch-Waxman framework. As Teva admitted, the only unexpired patents covering Copaxone are these process patents (the 40mg dosage frequency patents that it previously obtained to delay generic competition were invalidated). This means that whereas a new GA ANDA would no longer be delayed by Teva's patents, reclassifying Copaxone as a biologic could give Teva a new way to delay new generic competition through the process patents, which is exactly Teva's purpose.[37]

184. Moreover, Teva argued that reclassifying Copaxone as a biologic would cause A-rated generic GA to immediately cease to be automatically substitutable with Copaxone, thus extinguishing the current competition to Copaxone. For any generic GA product to regain its substitutable status, the FDA would have to take two distinct steps: (i) reclassify generic GA as a biological product under the PHSA; *and* (ii) determine that the generic GA product is "interchangeable" with Copaxone. Teva acknowledged this in its summary judgment arguments, stating, "[a]nd unlike generic drugs, biosimilars are not automatically substitutable; a pharmacy may substitute a biosimilar for the doctor-prescribed product only if FDA makes a determination of 'interchangeability.'" Teva complained that "FDA's refusal to transition COPAXONE allows Sandoz and Mylan to go on enjoying the benefits of automatic substitution at the pharmacy every

[37] In its order dismissing the case, the district court declined to resolve the question whether the BPCIA gives Teva the right to sue a biosimilar applicant based on process patents alone. Nonetheless, Teva's arguments still highlight its desperation to prevent any additional generic competition to Copaxone.

time a doctor writes a prescription for 'COPAXONE.'"[38] Thus, it was clear that Teva sought to prevent this automatic substitution, which is the means by which a generic effectively competes with a brand product under the Hatch-Waxman Act, with its latest bid for reclassification of Copaxone.

185. As of the date of this complaint, the FDA has not made the interchangeability determination for any biological product. Teva hoped that if its tactics succeed, there would be no generic automatic substitution, or at least that it would be delayed for a significant period of time, especially given the lack of precedent. During that time, Teva would be able to continue doing what it has been doing for decades—imposing supracompetitive prices on patients and payers.

186. The FDA's motion for summary judgment recognized the anticompetitive nature of Teva's lawsuit as part of its scheme to block generic competition. In particular, the FDA stated: "Teva Repeatedly Tries, and Fails, to Block Generic Competition to Copaxone."

187. Further, the FDA pointed out the hypocritical nature of Teva's arguments. Specifically, Teva argued that Copaxone is a protein because, among other things, it has a "specific, defined sequence" of amino acids. But as the FDA pointed out, in Citizen Petitions requesting that the FDA not approve GA ANDAs, Teva had previously argued that "*because of Copaxone's extensive sequence variability*, it was not possible for FDA to determine that a generic product had the 'same active ingredient'" (emphasis in original).[39] Similarly, the FDA had already considered and rejected Teva's arguments that Copaxone is a protein in denying Teva's Citizen Petitions requesting that the FDA not approve GA ANDAs, which denial was upheld by a district court in 2015 in a related case Teva filed against the FDA. Teva's

[38] Teva's argument is blatantly false given its misrepresentation campaign and anticompetitive agreements with PBMs and PBM-owned pharmacies, which were intended to and have been preventing generic substitution in a substantial share of the market.

[39] *See, e.g.*, Docket No. FDA-2008-P-0529 (Sept. 26, 2008) (arguing that "the clinically active polypeptide sequences in Copaxone® (glatiramer acetate injection) have not been sufficiently well defined" to enable a generic to show sameness of active ingredient with branded Copaxone).

inconsistent arguments and its effort to relitigate decided issues further highlight the repetitive and baseless nature of Teva's arguments. Teva's recent positions also undermine its previous positions taken in Citizen Petitions, regulatory filings, and court filings.

188. Indeed, on December 31, 2020, the district court granted the FDA's motion for summary judgment and dismissed Teva's lawsuit. In doing so, the court emphasized that this lawsuit was part of Teva's anticompetitive scheme to prevent generic competition to Copaxone:

- "[I]n the face of concerted resistance by Teva, the agency [FDA] approved generic glatiramer acetate products, including those manufactured by Sandoz and Mylan. Now, in yet another effort to stifle Copaxone competitors, Teva brings this lawsuit, seeking an order compelling FDA to regulate Copaxone as a 'biological product' under the Public Health Service Act ('PHSA'), 42 U.S.C. § 201 et seq., rather than as a 'drug' under the FDCA."

189. The court further noted the repetitive nature of Teva's arguments that Copaxone was a protein, emphasizing that the FDA had already repeatedly rejected these arguments. Moreover, like the FDA, the court called out the self-contradictory nature of Teva's arguments to serve its varying interests over the years. Specifically, the court contrasted (a) Teva's previous strenuous arguments that the sequences of the amino acid polymer chains in Copaxone are neither specific nor predefined, with (b) its position in the 2020 lawsuit that Copaxone has a "specific, defined sequence" and therefore constitutes a protein (and thus a biological product under the PHSA).[40]

190. Ultimately, the court upheld the FDA's determination that Copaxone was not a protein, consistent with Teva's own previous arguments (and contrary to Teva's arguments in this *post hoc* lawsuit). *See Teva Pharm. USA, Inc. v. FDA*, 2020 U.S. Dist. LEXIS 245082, at *87-88 (D.D.C. Dec. 31, 2020) ("Copaxone, a product consisting of a single type of molecule which, by Teva's own calculations, has anywhere between 10^{12} (one trillion) to 10^{29} (a trillion

[40] *Teva Pharm. USA, Inc. v. FDA*, 2020 U.S. Dist. LEXIS 245082, at *24-25 (D.D.C. Dec. 31, 2020).

times a trillion) possible sequences. Faced with this staggering potential for variation across entire copolymer chains, FDA reasonably concluded that the short replicated sequences between batches of glatiramer acetate do not give Copaxone a 'specific, defined sequence' as a whole." (citation omitted)).

191. While Teva's latest anticompetitive effort has failed (for now), it forced Mylan to intervene as a defendant and expend significant resources to defend against this baseless lawsuit alongside the FDA, when such resources could have been put to more beneficial uses. Meanwhile, the other components of Teva's on-going scheme, such as its misrepresentation campaign and anticompetitive agreements with PBMs and PBM-owned specialty pharmacies to exclude generic GA, continue to hamper generic competition to Copaxone.

X. TEVA'S CONDUCT HARMS MYLAN

A. Teva's Anticompetitive Scheme Harms and Will Continue to Harm Mylan

192. As a result of Teva's anticompetitive scheme, market entry of Mylan's generic GA was substantially delayed and significantly blunted. Each element of Teva's conduct caused harm to Mylan, and Teva's overarching scheme has been and will continue to be especially effective because the anticompetitive effects of the components feed into and amplify each other, such that the scheme as a whole caused and continues to cause compounded harm to Mylan.

193. But for Teva's conduct, Mylan's generic GA product would have entered the market significantly earlier. In particular, Teva's abuse of the regulatory processes before the FDA and court filings significantly delayed Mylan's launch. This delay from Teva's anticompetitive practices has resulted in significant lost sales for Mylan.

194. Further, but for Teva's conduct, Mylan would have secured additional sales of its generic GA product and captured substantially greater market share with its lower-priced generic GA product. Specifically, Teva's false and misleading statements regarding Mylan's GA product instilled, and are still causing, an ungrounded mistrust in patients and prescribers such that they

were unwilling to switch to Mylan's product despite its A-rated bioequivalent status (*i.e.*, FDA found that Mylan's product is bioequivalent to Copaxone). This buttressed Teva's misrepresentation campaign, which caused doctors to prescribe and patients to request Copaxone DAW, thus eviscerating the key mechanism for generic drugs to compete. Teva's illegal kickbacks to third-party foundations over time also enhanced the effect of the misrepresentation campaign by buying patient copays down to zero, thus removing their remaining incentive to switch to generic GA. At the same time, Teva's anticompetitive agreements with PBMs not to put generic GA on formularies and with PBM-owned specialty pharmacies not to dispense generic GA literally blocked generic GA from reaching consumers.

195. As a result of the components of Teva's anticompetitive scheme as described above, and especially the combined and amplified effect of the entire scheme, even Mylan's attempt to compete directly on prices by reducing the list price of generic GA 40mg by 60% in July 2018 failed to result in the degree of generic conversion normally expected in a competitive market. Evidence reflects that Mylan would not have been able to compete regardless of what price it offered due to Teva's conduct, and internal Teva emails demonstrate that that was Teva's intent.

B. Teva's False and Misleading Statements Harm Mylan

196. Teva's false and misleading statements have caused more prescribers to write DAW on Copaxone prescriptions, which prevents substitution of the Mylan GA product, than would have been the case absent such statements. This resulted in significant lost sales for Mylan.

197. Teva's misrepresentations about the efficacy of generic GA products, including Mylan's, and the availability of Mylan's copayment and nursing support programs have harmed and are continuing to harm Mylan. As the first generic entrant to the 40mg GA market, Mylan had the opportunity to capture a significant portion of that market but for Teva's conduct. The only other 40mg product, Sandoz's Glatopa, was not approved until February 2018, well after

Mylan entered the market, and since then has experienced supply chain issues leading to minimal distribution. However, Teva's false and misleading statements have artificially restricted Mylan's sales during this period, thus causing Mylan to lose sales and depriving consumers of lower-priced generic GA product.

198. Specifically, Teva's false and misleading statements have caused prescribers to write their Copaxone prescriptions as DAW at a much higher rate than they would have otherwise, thereby leading to significantly fewer sales of Mylan's GA product. Between October 2016 and September 2017, only approximately 13% of Copaxone prescriptions were written DAW. By February 2018 that percentage skyrocketed to at least 77%.

199. In addition, Teva's false and misleading statements forced Mylan to expend significant resources, which it otherwise would not have had to expend, to communicate with health care providers and patients to try to correct Teva's false and misleading statements.

200. Teva's false and misleading statements also irreparably harm Mylan by eroding prescriber and consumer confidence that Mylan's generic products will work as well and come with the same type of patient support as branded pharmaceutical products.

201. Due to the threatened and actual harm to Mylan's reputation and goodwill, Mylan has no adequate remedy at law.

202. On April 9, 2018, Mylan sent a cease and desist letter to the General Counsel of Teva North America, demanding that Teva cease its Copaxone misrepresentation campaign because it included the use of false and misleading statements to both patients and prescribers. On May 7, 2018, Teva responded that it had conducted an investigation of its promotional activities in connection with Copaxone, and denied any claims by Mylan.

203. Since receipt of Teva's response letter, Mylan sales reps continued hearing from Copaxone prescribers and their staffs that Teva was still making the same false and misleading statements.

MARKET POWER AND RELEVANT MARKET

204. At all relevant times Teva has and has maintained monopoly power and market power in the market for FDA-approved glatiramer acetate injection ("Copaxone Market"), which Teva markets and sells as the brand product Copaxone (collectively "Copaxone Products"). Teva's monopoly power and market power in the Copaxone Market includes monopoly power and market power over any narrower markets therein.

205. Copaxone Products includes A-rated generic equivalent glatiramer acetate injection products.

206. Teva's monopoly power and market power afford it the ability to control prices and exclude competitors. Direct evidence demonstrates that generic versions of Copaxone Products would have more quickly entered the market at substantial discounts to the brand versions but for Teva's anticompetitive conduct. Moreover, generic versions of Copaxone Products would have captured a larger portion of the market but for Teva's anticompetitive and deceptive conduct. Patients would have paid less for GA injection products, starting earlier in time, but for Teva's conduct. A small but significant non-transitory price increase in the price of Copaxone Products has never resulted in a significant loss of sales, nor would a future small but significant non-transitory price increase result in lost sales.

207. Teva did not and does not need to control or influence pricing for any other pharmaceutical product to maintain its monopoly power and market power over Copaxone Products.

208. Teva has sold and continues to sell Copaxone Products in excess of any measurement of competitive pricing and in excess of Teva's marginal cost. Teva has experienced atypically high profit margins for Copaxone Products. For example, as the Congressional investigation revealed, from 2013 to 2018, Teva's costs to manufacturer Copaxone "declined significantly" while it raised prices. Teva's cost of goods sold for Copaxone was between 0.5% and 3% of the medicine's net price.

209. In addition to direct evidence of monopoly power and market power, indirect evidence also establishes monopoly power and market power. Copaxone Products exhibit high barriers to entry, including the costs of developing glatiramer acetate injection products, patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and A-rated generic substitution laws.

210. For a significant period of time even after generic entry, Teva's share of the Copaxone Market remained above 75% and, at times, Teva has controlled 100% of the Copaxone Market.

211. Copaxone Products are not reasonably interchangeable with any other drugs except for A-rated generic versions of Copaxone Products.

212. The existence of other FDA-approved RRMS disease-modifying treatments has not significantly constrained Teva, and Teva has been increasing the prices for Copaxone over the years even when new RRMS injectable disease-modifying therapies were approved.

213. Manufacturers differentiate between brand drugs like Copaxone to doctors and patients based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Copaxone vis-à-vis other treatments for RRMS. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Copaxone.

214. Unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the prescribing decision for prescription drugs is made by the prescriber, not consumers of these products. Additionally, once the prescriber and patient find a product that is well-tolerated, it is very unlikely that the patient will switch to a different MS treatment (that is not a generic of the current therapy) based on variations of price.

215. The United States and its territories are the relevant geographic market.

ANTITRUST IMPACT

216. Teva's anticompetitive scheme to maintain its monopoly in the Copaxone market through abuse of the regulatory processes and court filings, anticompetitive agreements and tying of rebates, DAW campaign through false and misleading statements, agreements with PBMs to exclude generic GA from formularies and with PBM-owned specialty pharmacies to exclude generic GA from dispensing, and paying off patient copay through illegal kickbacks to third-party foundations, has denied consumers the benefits of generic competition for Copaxone contemplated by the Hatch-Waxman Act. Teva's scheme to protect and extend its monopoly power in the Copaxone Market has been multi-faceted and diverse, but the cumulative effect has been consistent: Teva has successfully and illegally insulated itself from competition. Teva illegally maintained and extended its monopoly power through exclusionary conduct completely unrelated to its ability to compete on a level playing field. This has caused payers and consumers to overpay at least hundreds of millions of dollars in overcharge for Copaxone.

217. By engaging in this scheme, Teva first delayed generic entry through its repetitive and continuous abuse of the regulatory processes and court filings.

218. Second, concurrent with its abuse of the regulatory processes and court filings to delay generic entry, Teva effectuated a market shift from 20mg Copaxone to 40mg Copaxone, which effectively inhibited generic competition when the FDA approved 20mg GA. As a recent study found, U.S. spending on Copaxone and GA did not decrease with generic entry only for the 20mg dosage in 2015-2017. Rather, only after generic entry for the 40mg dosage began in late 2017 did prices decrease by 47%-64%, and spending decreased from $962 million/quarter in 2015 to $508 million/quarter in 2019.[41]

[41] Rome et al., *US Spending Associated With Transition From Daily to 3-Times-Weekly Glatiramer Acetate*, JAMA Internal Med. 2020, 180(9):1165-1172 (July 20, 2020), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2770468?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamainternmed.2020.2736.

219. Third, Teva engaged in a campaign of false and misleading statements to prevent generic GA uptake. Teva's misrepresentations, including that generic GA was not as effective as Copaxone, and that generics do not offer copay or nursing support for generic GA, were false and have jeopardized competition on the merits from generic GA. Through these false and misleading statements, as well as other marketing ploys, Teva operated a misrepresentation campaign that caused doctors to prescribe and patients to request DAW prescriptions, thus obstructing generic GA uptake. Specifically, as a result of Teva's misrepresentation campaign, the rate of DAW prescriptions increased from approximately 13% throughout the year before generic GA 40mg launched to at least 77% just 4 months thereafter.

220. Fourth, Teva carried out its "House Brand" strategy to exclude generic GA from formularies and dispensing. As part of this strategy, Teva went beyond standard rebating practices by entering into all-or-nothing rebate agreements with key PBMs to exclude generic GA from formularies and to prevent PBM-owned specialty pharmacies from dispensing generic GA, even when the prescription specifically calls for generic GA instead of branded Copaxone and even when generic GA was covered in formulary. This subverts automatic substitution laws, which are designed to facilitate generic competition with brand drugs at the pharmacy level.

221. Fifth, Teva further removed patients' incentive to switch to generic GA by paying off their copay obligations through illegal kickbacks to third-party foundations. This removal of incentives to switch compounds the effect of the misrepresentation campaign and further inhibits generic GA uptake.

222. Finally, by continuing its strategy of abusing regulatory processes and court filings through a baseless lawsuit against the FDA to reclassify Copaxone as a biologic and using arguments that contradicted Teva's own previous positions, Teva continued to seek to completely eliminate generic competition to Copaxone in the near future. While this latest effort was rejected by the court, it has forced generic GA manufacturers to incur significant expenses to defend alongside the FDA.

223. Teva's anticompetitive scheme has had a direct, substantial, and adverse effect on Mylan and competition by monopolizing and maintaining monopoly power, increasing prices, artificially creating barriers to entry, and foreclosing competition in the Copaxone market. But for Teva's conduct, Mylan would have been able to enter the Copaxone market and compete for sales within the Copaxone market substantially earlier and to obtain more market share upon entry. This delay in competition is exactly what Teva intended to, and did, cause through its unlawful scheme. If Teva had not engaged in the anticompetitive conduct designed to exclude generic GA and prevent its uptake, including the DAW campaign through false and misleading statements about generic GA, paying off patient copay through illegal kickbacks to third-party foundations, and agreements with PBMs and PBM-owned specialty pharmacies to exclude generic GA from formularies and dispensing, Mylan would have been able to capture a larger market share upon entry and thereafter.

224. Because Mylan's competing generic GA was priced below Teva's Copaxone, Mylan would have been able to instantly capture a significant portion of sales, thus lowering prices for consumers and payers. Mylan is a sophisticated generic pharmaceutical manufacturer with extensive experience in obtaining ANDA approval and launching generic versions of branded pharmaceutical products for prices significantly below brand pricing. However, as a result of the components of Teva's anticompetitive scheme as described above, and the combined and amplified effect of the entire scheme, even Mylan's attempt to compete directly on prices by reducing the list price of generic GA 40mg by 60% in July 2018 failed to result in the degree of generic conversion normally expected in a competitive market.

225. By impeding competition from generic GA products, including Mylan's, Teva's anticompetitive scheme has allowed (and unless restrained by this Court, will continue to allow) Teva to maintain and extend its monopoly power in the relevant market and to sell Copaxone at artificially inflated monopoly prices. For example, a Teva employee reported to the General Manager of Teva Neuroscience in 2016 that "you can definitely see a trend in the increase in OOP [out of pocket] costs that the payers are shifting to patients and some of this may be our

price increases as well."[42] Similarly, Congress' investigation revealed that "[e]ven Teva's own employees could not afford Copaxone at its price. In one July 2018 exchange, a Teva employee explained that she could no longer afford Copaxone because she would have to pay $1,673.33 out of pocket as compared to $12 for Mylan's generic. Ultimately, Teva gave the employee free product, a solution unavailable to most Copaxone patients."[43]

226. Teva's anticompetitive scheme has harmed the competitive process and allowed Teva to perpetuate supracompetitive prices against wholesalers, retailers, payers, and consumers. But for Teva's anticompetitive conduct, consumers and federal, state, and private payers would have enjoyed the benefits of lower-priced generic competition years earlier. Instead, as a result of Teva's strategies to thwart generic entry, consumers and federal, state, and private payers have been, and unless Teva is restrained by this Court, will continue to be, forced to pay monopoly rents for Teva's branded Copaxone in the magnitude of hundreds of millions of dollars in overcharge. The impact of Teva's conduct is felt throughout the health care industry, impacting pharmaceutical competitors, health care providers, insurers and other direct purchasers, intermediaries, and consumers.

227. Further, the existence of each of the components of Teva's anticompetitive scheme described above, and especially the accumulation of the foregoing, can act as a disincentive for generics considering whether and when to aggressively pursue submission and/or approval of a particular ANDA. Any obstacle, such as combating false and misleading statements, forced generic manufacturers, including Mylan, to expend significant resources to combat Teva's anticompetitive tactics. For example, this is true with respect to the resources that the generics would need to expend in correcting the false and misleading statements about the generic product. Further, the use of misrepresentations to increase the rate of DAW prescriptions improperly circumscribes substitution laws that were designed to facilitate competition from generic drugs.

---

[42] House Teva Report, *supra* note 1, at 9.
[43] *Id.* at 10.

228. ANDA filers are less likely to aggressively pursue the filing or approval of ANDAs when faced with these added hurdles and complications.

229. Teva's anticompetitive conduct as alleged herein is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine.

230. There are and were no legitimate, procompetitive justification for Teva's anticompetitive conduct. Even if there were some conceivable and cognizable justification, Teva's conduct was not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the scheme's anticompetitive effects on Mylan, competition, and consumers.

231. Each component of Teva's scheme and the overall scheme are separately actionable under federal and state antitrust laws.[44] Moreover, by way of the ingenuity, complexity, duration, and surreptitious nature of Teva's conduct, the overall scheme was unknown to Mylan – and could not have been known to Mylan – until the release of the House Teva Report. Teva's scheme was inherently self-concealing, and Teva employed deceptive tactics and techniques of secrecy to avoid detection of, and to fraudulently conceal, its scheme to protect, maintain, and extend its monopoly. Upon information and belief, Teva's contracts with PBMs to exclude generics contained confidentiality clauses that prevented Mylan from discovering Teva's unlawful conduct, and Teva took steps to conceal its entire monopolization scheme even from its own employees (in addition to its efforts to conceal the House Brand Strategy from its own employees, as detailed earlier in this Complaint).

232. The overarching scheme described throughout the complaint constitutes a continuing violation and Mylan's claims are not time-barred.

[44] Mylan is not, at this time, alleging that Teva's introduction of Copaxone 40mg by itself was anticompetitive, but believes it was an important part of detailing Teva's history with these products. Mylan reserves all rights as discovery may uncover facts that could justify including this as separately illegal conduct.

COUNT I

MONOPOLIZATION AND ATTEMPTED MONOPOLIZATION

233. Mylan repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

234. The Copaxone Market is the relevant market.

235. Teva possesses monopoly power in the Copaxone Market. This market is characterized by significant barriers to entry.

236. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Teva has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize, and maintaining its monopoly of the Copaxone Market.

237. Through the foregoing acts, Teva, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use its power in the Copaxone Market to monopolize, attempt to monopolize, and maintain its monopoly of the Copaxone Market.

238. Teva knowingly and intentionally engaged in an anticompetitive scheme designed to unlawfully delay market entry of an A-rated generic version of Copaxone and to unlawfully hinder generic adoption of an A-rated generic version of Copaxone, and thus to willfully maintain its monopoly power. First, Teva abused the regulatory processes before the FDA and court filings to delay generic entry. Second, Teva switched the market from 20mg Copaxone to 40mg Copaxone to harm generic competitors and reduce the competitive benefits of A-rated generic entry. Third, Teva embarked on a campaign of false and misleading promotional statements aimed at preventing consumers and doctors from adopting A-rated generic GA. This conduct, along with other marketing tactics, enabled Teva's campaign to cause doctors to prescribe and patients to request Copaxone DAW, which circumvents laws mandating or permitting automatic substitution of generic GA. Fourth, Teva went beyond common rebating

practices and entered into all-or-nothing rebate agreements with PBMs to exclude generic GA from formularies and to prevent PBM-owned specialty pharmacies from dispensing generic GA even if it was prescribed and covered on formulary. Fifth, Teva used illegal kickbacks to third-party foundations to pay off patients' copay obligations, thus further removing any incentive to switch to generic GA. Finally, Teva continued its strategy of abuse of regulatory processes and court filings and filed a baseless lawsuit against the FDA making self-contradictory arguments to seek to reclassify Copaxone as a biologic to eliminate all generic competition in the near future.

239. Teva engaged in this anticompetitive scheme and each of the component conduct with the specific intent to unlawfully delay market entry of an A-rated generic version of Copaxone and to unlawfully hinder sales of an A-rated generic version of Copaxone, and thus to willfully maintain its monopoly power.

240. Teva's scheme and component conduct have no procompetitive, legitimate business justification. Teva's scheme and conduct can only be explained by anticompetitive motives and a desire to foreclose competition in the Copaxone Market. For example, there is no legitimate business justification for pricing the new and improved 40mg Copaxone formulation lower than the existing formulation or raising the price of the 20mg. The only justification for this practice is Teva's desire to convert the Copaxone Market from the 20mg formulation to the 40mg formulation ahead of generic entry, and thus blunt the effectiveness of that entry and harm the generic entrants. Similarly, there is no legitimate business rationale for making false and misleading statements about Mylan's GA, or entering into agreements with PBMs and PBM-owned specialty pharmacies to condition the payment of any rebates at all on the exclusion of lower-priced generic GA and to prevent PBM-owned specialty pharmacies from dispensing generic GA. The only justification for these and other practices is Teva's desire and specific intent to prevent sales of Mylan's GA product.

241. To the extent there are legitimate business justifications for Teva's exclusionary conduct, Teva's anticompetitive conduct is not necessary to serve those justifications.

242. At all relevant times, Teva enjoys monopoly power in the Copaxone Market, and there is a dangerous probability Teva will succeed in maintaining its monopoly power by means of its unlawful conduct, including by delaying generic entry through abuse of regulatory processes and court filings, by switching the market from 20mg to 40mg, and by limiting generic uptake through the misrepresentation campaign, agreements with PBMs and PBM-owned specialty pharmacies to exclude lower-priced generic GA from formularies and dispensing, and anticompetitive use of illegal kickbacks.

243. By its scheme, Teva intentionally and wrongfully maintained and attempted to maintain monopoly power with respect to Copaxone in violation of Section 2 of the Sherman Act. As a result of Teva's unlawful actual and attempted maintenance of monopoly power, Mylan has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

244. Teva's unlawful conduct as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Copaxone Products was restrained, suppressed and eliminated;
- Purchasers of Copaxone Products were deprived of the benefits of free and open competition, and the availability of a lower cost generic GA product, in the purchase of Copaxone Products; and
- Teva sold, and will continue to sell, its Copaxone at artificially high and supracompetitive price levels.

245. Teva's conduct occurred in, and has had a substantial effect on, interstate commerce.

246. Teva's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is of the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

247. Teva's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

248. Mylan is entitled to a judgment that Teva has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Teva's continued violations.

COUNT II

VIOLATION OF THE LANHAM ACT (15 U.S.C. § 1125(a)(1)(B))

249. Mylan repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

250. Teva's activities as described above constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

251. Teva has made, and will continue to make if not enjoined, false or misleading descriptions of fact or representation of fact in a commercial adverting or promotion in interstate commerce by and through at least Teva's sales representatives and Shared Solutions about the nature, characteristics and/or qualities of Teva's Copaxone, Mylan's GA product, and Mylan's patient hub services.

252. Teva's false or misleading statements have entered into interstate commerce. On information and belief, Teva has directed its campaign of misinformation nationwide from its New Jersey headquarters.

253. Teva's false and misleading statements have actually deceived and/or have a tendency to deceive a substantial segment of the relevant public to whom the statements have been made, including numerous GA prescribers and MS patients.

254. Teva's false and misleading statements have influenced and/or are likely to influence medical professionals' decisions to prescribe or allow substitution of Mylan's 40mg GA and patients' decisions to use Mylan's 40mg materially and negatively.

255. As discussed above, numerous medical professionals have repeated Teva's false statements that, among other things, Mylan's GA is only 80% or 85% as effective as Copaxone, that Mylan does not offer copay support, or does not offer training and nursing support to patients. Doctors and nurses' willingness to repeat Teva's false statements shows that they have been actually misled by them.

256. Because medical professionals and MS patients have been deceived by Teva about the quality of Mylan's GA and related services, medical professionals have refused to prescribe Mylan's GA, and have written Copaxone prescriptions DAW so that their patients either will not be switched to Mylan's GA, or will be switched back to branded Copaxone.

257. By reason of the foregoing, Teva has intentionally and willfully violated 15 U.S.C. § 1125(a)(1)(B).

258. As an actual and proximate result of Teva's conduct described herein, Mylan has suffered monetary damages in an amount to be proven at trial.

259. Teva's aforesaid acts also have caused, and unless restrained and enjoined by this Court, will continue to cause, irreparable damage, loss, and injury to Mylan in the form of loss of prescriber and patient confidence and loss of goodwill for which Mylan has no adequate remedy at law. Mylan is entitled to an injunction, pursuant to 15 U.S.C. § 1116(a), to prevent Teva from continuing to make the false and misleading representations and for corrective advertising.

260. Mylan is entitled, pursuant to 15 U.S.C. § 1117, to recover from Teva: (i) Teva's profits from its unfair competition and false advertising, (ii) damages Mylan has sustained due to Teva's conduct, and (iii) the costs of this action.

261. Because this is an exceptional case involving calculated and willful misconduct by Teva, Mylan is also entitled, pursuant to 15 U.S.C. § 1117(a)(3), to recover (i) up to three times the amount of actual damages and (ii) attorneys' fees.

COUNT III

TORTIOUS INTERFERENCE WITH PROSEPCTIVE CONTRACTUAL RELATIONS OR PROSPECTIVE ECONOMIC BENEFIT

262. Mylan repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

263. Mylan develops and sells pharmaceutical products in the commerce of the State of New Jersey.

264. Teva's conduct gives rise to common law liability for tortious interference with a contract or prospective economic benefit.

265. Mylan had a reasonable expectation of economic benefit from a prospective contractual and economic relationships with thousands of purchasers, pharmacies and MS patients across the country, all of whom would purchase its generic GA product.

266. Teva has been aware of Mylan's intention to market a generic GA product since at least mid-2009. Accordingly, Teva is aware of Mylan's reasonable expectation of economic benefit from prospective sales of its generic GA product.

267. In connection with its anticompetitive scheme, including its component conduct, alleged above, Teva had the purpose or intent to harm Mylan by preventing relationships from occurring with prospective contractual and economic relationships with thousands of purchasers, pharmacies and MS patients across the country, all of whom would purchase Mylan's generic GA product.

268. Teva employed wrongful means and acted solely out of malice or relied upon dishonest, unfair, and improper acts in interfering with Mylan's prospective business relations.

269. Teva had no privilege or justification relating to its actions.

270. If Teva had not interfered, Mylan would not be deprived of its benefit from the prospective contractual and economic relationships with purchasers, pharmacies, and consumers, or delayed in entering the relevant market, and would receive the anticipated benefit of sales and profits from generic entry.

271. Teva's aforementioned acts have caused, and unless restrained and enjoined by this Court, will continue to cause, irreparable damage, loss, and injury to Mylan for which Mylan has no adequate remedy at law. Mylan is entitled to an injunction to prevent Teva from continuing its illegal conduct.

272. Teva's tortious interference has directly and proximately caused injury to Mylan's business and property, including but not limited to lost profits and lost business opportunities. As a result of Teva's improper conduct, Mylan suffered actual damages in an amount to be determined at trial.

273. Teva's conduct as complained of herein was malicious, wanton, oppressive, reckless, and in willful disregard of the Mylan's rights (as well as those of pharmacies and patients), thereby warranting the imposition of punitive damages in order to deter similar unlawful conduct by Teva in the future.

COUNT IV

UNFAIR COMPETITION

274. Mylan repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

275. By reason of the foregoing unlawful, predatory and anticompetitive acts as alleged herein, Teva has engaged in unfair competition and/or unfair trade practices in violation of the common law of the State of New Jersey.

276. Further, with respect to the misrepresentation campaign, in connection with the marketing of Copaxone, Teva made representations regarding the effectiveness of generic GA.

277. Teva's representations about the effectiveness of generic GA were likely to deceive or mislead medical professionals and MS patients to the likely commercial detriment of Mylan.

278. Teva's representations were material, in that they were likely to affect the conduct of prospective purchasers.

279. There is a reasonable basis for believing that Teva's representations caused or likely will cause a diversion of trade from Mylan to Teva and harm to Mylan's reputation and good will.

280. Teva's aforesaid acts have caused, and unless restrained and enjoined by this Court, will continue to cause, irreparable damage, loss, and injury to Mylan for which Mylan has no adequate remedy at law. Mylan is entitled to an injunction to prevent Teva from continuing its illegal conduct.

281. As a result of Teva's improper conduct, Mylan has suffered actual damages in an amount to be determined at trial, and is entitled to damages, attorneys' fees, costs of suit and other appropriate relief.

282. Teva's conduct as complained of herein was malicious, wanton, oppressive, reckless, and in willful disregard of the Mylan's rights, thereby warranting the imposition of punitive damages in order to deter similar unlawful conduct by Teva in the future.

COUNT V

TRADE LIBEL

283. Mylan repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

284. Teva made numerous false statements about the services Mylan provides in connection with its GA product including, among other things, that Mylan does not offer training and nursing support or copay support for its GA product.

285. Teva intended the publication of such statements to cause pecuniary loss to Mylan or reasonably should have recognized that publication of its statements would cause pecuniary loss to Mylan.

286. As a result of Teva's false statements described herein Mylan suffered actual pecuniary loss, in an amount to be determined at trial.

287. Teva made its statements with actual malice. Teva knew the statements were false or acted in reckless disregard of their truth or falsity.

288. Teva's aforesaid acts have caused, and unless restrained and enjoined by this Court, will continue to cause, irreparable damage, loss, and injury to Mylan for which Mylan has no adequate remedy at law. Mylan is entitled to an injunction to prevent Teva from continuing its illegal conduct.

289. Teva's conduct as complained of herein was malicious, wanton, oppressive, reckless, and in willful disregard of Mylan's rights, thereby warranting the imposition of punitive damages in order to deter similar unlawful conduct by Teva in the future.

COUNT VI

THE NEW JERSEY ANTITRUST ACT, N.J.S.A. 56:9-4

290. Mylan repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

291. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. 56:9 et seq., and seeks a judgment that Teva's conduct as alleged herein has violated New Jersey Antitrust Act, N.J. Stat. Ann. 56:9-4 – Monopolization.

292. Teva's conduct as alleged herein constitutes monopolization, attempted monopolization, and maintenance of monopoly in violation of N.J. Stat. Ann. 56:9-4.

293. Specifically, Teva's anticompetitive scheme, including abuse of the regulatory processes and court filings, shifting of the market to 40mg through irrational pricing,

anticompetitive agreements and tying of rebates, DAW campaign through false and misleading statements, agreements with PBMs and PBM-owned specialty pharmacies to exclude lower-priced generic GA from formularies dispensing, paying off patient copay through illegal kickbacks to third-party foundations, and its component conduct are calculated to maintain monopoly power in the relevant market, in violation of N.J. Stat. Ann. 56:9-4.

294. Teva's unlawful conduct as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Copaxone Products was restrained, suppressed and eliminated;
- Purchasers of Copaxone Products were deprived of the benefits of free and open competition, and the availability of a lower cost generic GA product, in the purchase of Copaxone Products; and
- Teva sold, and will continue to sell, its Copaxone at artificially high and supracompetitive price levels.

295. Teva's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is of the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

296. Teva's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

297. Mylan is entitled to a judgment that Teva has violated Section 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Teva's continued violations.

JURY DEMAND

298. Mylan demands a jury trial as to all issues that are triable by a jury in this action.

PRAYER FOR RELIEF

WHEREFORE, Mylan respectfully requests that this Court enter judgment against the Defendants as follows:

a. Issuing a preliminary and permanent injunction ordering that Teva and its agents, employees, or representatives, and all persons acting in concert or participating with it, are commanded, enjoined, or restrained, directly or indirectly, by any means whatsoever, from falsely directly or indirectly using in commerce or causing to be published or otherwise disseminated in any form of promotional materials or activities any false or misleading representation concerning Mylan's GA and related services, including that generic GA products are only 80% or 85% as effective as Copaxone, that Mylan does not offer copay support, and that Mylan does not offer training and nursing support in connection with its GA;

b. Issuing a permanent injunction ordering that Teva engage in appropriate corrective advertising at its own expense, reasonably designed to reach all persons to whom the false and misleading statements made by Teva were directly or indirectly disseminated, and retracting the false, misleading, and unfair statements previously made to the extent necessary to correct any misperceptions resulting from its unlawful acts complained of herein;

c. Issuing a preliminary and permanent injunction enjoining Teva from all anticompetitive conduct alleged herein, including but not limited to the false and misleading statements described above, agreements with PBMs to exclude generic GA products from formularies and for PBM-owned specialty pharmacies to exclude generic GA products from dispensing, anticompetitive use of illegal kickbacks to third-party foundations, and its baseless lawsuit against the FDA seeking to reclassify Copaxone as a biologic;

d. Declaring that Teva's agreements with PBMs to exclude generic GA products from formularies and with PBM-owned specialty pharmacies to exclude generic GA products from dispensing are unenforceable as a violation of the applicable laws;

e. Awarding Mylan:

i. Damages in an amount to be proven at trial, such damages to be trebled pursuant to 15 U.S.C. § 1117, 15 U.S.C. § 15 and/or N.J. Stat. Ann. 56:9-12;

ii. All of Teva's profits derived by reason of the unlawful acts complained of above, such damages to be trebled pursuant to 15 U.S.C. § 1117;

iii. Exemplary and punitive damages as appropriate to deter any future willful misconduct by Teva in reckless disregard of Mylan's rights;

iv. Pre and post-judgment interest on the foregoing sums;

f. Ordering Teva to pay Mylan's reasonable attorneys' fees, costs and disbursements of this action; and

g. Granting such further and other relief as the Court deems just and proper.

Dated: June 29, 2021

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Mylan Pharmaceuticals Inc.

s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)
Jakob B. Halpern (jhalpern@saiber.com)
Catherine Soliman (csoliman@saiber.com)
Saiber LLC
One Gateway Center, Suite 950
Newark, NJ 07102
T: (973) 622-3333
F: (973) 286-2465

Stuart A. Williams (swilliams@wsgr.com)
Michael S. Sommer (msommer@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI, P.C.
1301 Avenue of the Americas, 40th Floor
New York, NY 10019
Telephone: (212) 999-5800
Facsimile: (212) 999-5899

Seth C. Silber (ssilber@wsgr.com)
Brendan J. Coffman (bcoffman@wsgr.com)
Thu V. Hoang (thoang@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI, P.C.
1700 K Street NW, 5th Floor
Washington, DC 20006
Telephone: (202) 973-8800
Facsimile: (202) 973-8899

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel hereby certifies that this matter in controversy is the subject of no other matter pending in this Court.

Dated: June 29, 2021

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Mylan Pharmaceuticals Inc.

s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)
Jakob B. Halpern (jhalpern@saiber.com)
Catherine Soliman (csoliman@saiber.com)
Saiber LLC
One Gateway Center, Suite 950
Newark, NJ 07102
T: (973) 622-3333
F: (973) 286-2465

Stuart A. Williams (swilliams@wsgr.com)
Michael S. Sommer (msommer@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI, P.C.
1301 Avenue of the Americas, 40th Floor
New York, NY 10019
Telephone: (212) 999-5800
Facsimile: (212) 999-5899

Seth C. Silber (ssilber@wsgr.com)
Brendan J. Coffman (bcoffman@wsgr.com)
Thu V. Hoang (thoang@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI, P.C.
1700 K Street NW, 5th Floor
Washington, DC 20006
Telephone: (202) 973-8800
Facsimile: (202) 973-8899

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel hereby certifies that the within Complaint seeks both monetary damages greater than $150,000 and injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: June 29, 2021

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Mylan Pharmaceuticals Inc.

s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)
Jakob B. Halpern (jhalpern@saiber.com)
Catherine Soliman (csoliman@saiber.com)
Saiber LLC
One Gateway Center, Suite 950
Newark, NJ 07102
T: (973) 622-3333
F: (973) 286-2465

Stuart A. Williams (swilliams@wsgr.com)
Michael S. Sommer (msommer@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI, P.C.
1301 Avenue of the Americas, 40th Floor
New York, NY 10019
Telephone: (212) 999-5800
Facsimile: (212) 999-5899

Seth C. Silber (ssilber@wsgr.com)
Brendan J. Coffman (bcoffman@wsgr.com)
Thu V. Hoang (thoang@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI, P.C.
1700 K Street NW, 5th Floor
Washington, DC 20006
Telephone: (202) 973-8800
Facsimile: (202) 973-8899